

*United States Court of Appeals
for the Second Circuit*



APPENDIX

NO. 74-1999

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

-against-

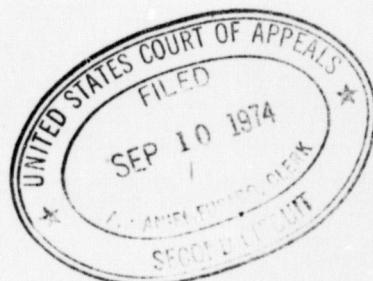
DIAPULSE CORPORATION OF AMERICA,
also known as THE DIAPULSE MANU-
FACTURING CORPORATION OF AMERICA,
a corporation,

Defendant-Appellant.

On Appeal from the United States District
Court for the Eastern District of New York

APPELLANT'S APPENDIX

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RELEVANT DOCKET ENTRIES

68C 391

UNITED STATES OF AMERICA

vs.

DIAPULSE CORPORATION OF AMERICA also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation

Basis of Action: UNDER SECTION 302 (a) of the FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. 332(a), etc.

Seeks: INJUNCTION, ETC.

4/25/68 COMPLAINT FILED

1

* * *

5/2/68 By MISHLER, J.- PRELIMINARY INJUNCTION FILED. It is ordered that pltf's motion for preliminary injunction ret. 5/6/68 is withdrawn; and it is further ordered that deft Diapulse etc. are restrained and enjoined pending trial and determination of this action etc. (P/C mailed to attys)

9

5/14/68 ANSWER of deft filed. (affid of srv by mail on 5/13/68)

10

* * *

12/8/71 By ROSLING, J.- DECISION RENDERED, Constituting Findings of Fact and Conclusions of law filed. It is ordered that until the entry of a final judgment etc. is entered by this Court modifying the preliminary injunction etc. the deft Diapulse Corporation of America etc. are restrained and enjoined etc. (copy forwarded U.S. Atty and copy mailed to Atty Gen.)

62

* * *

6/12/72 By Rosling, J.-Opinion of 6/9/72 incorporating court's findings of fact & conclusions of law & directing that parties serve proposed amendments to within & proposed judgment by 6/26/72 & file same by 6/30/72 filed. (Copy given to U.S. Atty & mailed to Atty Genrl.)

107

* * *

7/18/72 By Rosling, J.-Permanent Injunction dtd 7/15/72 filed. Pltff-U.S.A. to recover costs of deft when taxed. (P/C mailed to attys)

110

* * *

5/7/74 By DOOLING, J.,- Memorandum incorporating findings of fact and order dtd 5-7-74 ordering modification of injunction etc. filed

149

7/2/74	Memorandum in support of govt's proposed permanent injunction, etc. filed	150
7/3/74	Before DOOLING, J.-Case called - Govt's proposed injunction argued- Deft's proposed injunction argued- Decision reserved	
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7/18/74	By DOOLING, J.-ORDER AND JUDGMENT dtd 7-17-74 granting permanent injunction against deft with costs to be taxed against deft by the Clerk filed. (P/c mailed to attys)	153
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7/23/74	Notice of Appeal filed. Duplicate mailed to C of A with copy of docket entries and duplicate of notice sent to pltff	155
7-24-74	Certified copy of permanent injunction returned and filed executed	156

FINDINGS OF FACT AND CONCLUSIONS OF LAW 12/8/71

ROSLING, J.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----x
UNITED STATES OF AMERICA,

Plaintiff,

-against-

68-C-391

DIAPULSE CORPORATION OF
AMERICA, a/k/a/ THE DIAPULSE
MANUFACTURING CORPORATION OF
AMERICA, a corporation,

Dec 8 1971

Defendant.

-----x
Appearances:

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Of Counsel

BASS & ULLMAN, ESQS.
Attorneys for Defendant

Milton A. Bass, Esq.
Of Counsel

Decision Constituting Findings
of Fact and Conclusions of Law

Rosling, J.

I

Plaintiff having moved for a preliminary injunction
herein by notice of motion returnable on November 5, 1971,

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2.

and the papers, proceedings and evidence recited below having been before the court at the time of the signing of this order and having been found by the court a sufficient basis for the granting of such injunction, to wit:

1. Judgment entered March 31, 1967, in the United States District Court, District of Connecticut, Admiralty No. 4818, an in rem action, entitled, United States of America v. An article of device consisting of 1 device, more or less labeled in part: (metal plate on device) "Diapulse Serial No. 1824 Model D * * * Diapulse Manufacturing Corporation of America New York City" etc., copy of which judgment is hereunto annexed and incorporated by reference herein.

2. Order of the said district court, United States District Judge M. Joseph Blumenfeld, April 25, 1967 and filed on April 26, 1967, on a motion made by the Diapulse Corporation of America (hereinafter "Diapulse Corp.") to amend said judgment, copy of said order being hereunto annexed and incorporated by reference herein.

3. The affirmance on January 30, 1968, by the Court of Appeals of the Second Circuit of said judgment as so amended, on the appeal of Diapulse Corp. and the opinion of the Court of Appeals upon such affirmance (389 F.2d 612).

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4. The denial of certiorari by the Supreme Court on June 10, 1968, 392 U.S. 907.

5. Following denial of certiorari defendant, on June 4, 1969, served a notice of motion returnable before Judge Blumenfeld, for an order further amending the amended Connecticut judgment by decreeing that the device had been brought into compliance with the law when labeled as being an adequate and effective treatment for tissue and bone healing, sinusitis, bursitis, arthritis and blood flow to peripheral areas. The notice of motion was endorsed in its margin on June 24, 1969, "Motion Denied." Said notice of motion and endorsement, copy annexed and incorporated herein by reference, are among the exhibits considered by the court as basis for the grant of a preliminary injunction.

6. The commencement of this action by the filing of the complaint against Diapulse Corp. on April 25, 1968, and the commencement of suit by the service of process on said Diapulse Corp. on April 25, 1968, and the pleadings in the action.

7. The service by plaintiff of an order made by a judge of the Eastern District of New York returnable May 6, 1968, to show cause why a preliminary injunction should not issue, the order made on May 2, 1968, by Chief Judge Mishler

ROSLING, J.

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of this court granting a partial preliminary injunction on consent of Diapulse Corp.

8. The testimony taken and exhibits introduced before this court upon an evidentiary hearing thus far held on the following dates in 1971:

Plaintiff's case: June 7, 8, 9, 10, 11, 14, 15, 16, 17, 21, 22; October 12, 14, 15, 18, 19, 20, 21, 22, 26.

Defendant's case: October 27, 28; November 1, 2, 3, 4, 5, 8, 9, 10, 11, 15, 16, 17, 18, 19, 22, 23, 24, 26 and 29.

9. The testimony and exhibits comprising the record of the in rem trial in Connecticut referred to in paragraphs "1" and "?" which were introduced by the Government as an exhibit in this case.

10. An order signed on November 8, 1971, by the court on its own motion pursuant to 28 U.S.C. § 65(a)(2), which consolidated the trial of the action with the hearing of the motion for a preliminary injunction.

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II

The court estimates that the record of this trial and hearing, when fully transcribed, plus the exhibits will substantially exceed 10,000 pages. A minimum of six months will be required for the complete transcription and proof-reading of the minutes, the exchange and filing of briefs by the attorneys, the court's review of the transcript, exhibits and briefs, its independent research, and the drafting and filing of its opinion.

The foregoing considerations led the court, when a break in the trial on November 5, 1971, occasioned by defendant's temporary unreadiness to proceed with the production of witnesses provided the opportunity, to hear argument from counsel on the plaintiff's motion for a preliminary injunction, and in granting it, to inform the attorneys for the parties that the court would consider its decision tentative, subject to modification or recall should the incoming testimony to the moment of actual signature of the order granting such preliminary injunction justify such action.

ROSLING, J.

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III

On the basis of the evidence adduced up to the close of the trial on November 29, 1971, the following appears:

11. The Diapulse Corp. did not bring the seized Diapulse device into compliance with the requirements of the Food and Drug Administration pursuant to the order in the Connecticut suit, made April 25, 1967, amending the judgment entered March 31, 1967, and is, accordingly subject, among other provisions, to subparagraph 4 of the third ordering paragraph of said order reading as follows:

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"4. The Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of said article until a duly authorized representative of the Department of Health, Education and Welfare shall have had free access thereto in order to take any sample or make any tests or examinations that are deemed necessary, and shall in writing have released such article for shipment, sale, or other disposition."

12. The Diapulse devices held, manufactured and disposed of by the Diapulse Corp. for a number of years prior to and on and after March 31, 1967, and to the date hereof, were and are substantially similar to the device declared forfeited for misbranding and misrepresentation in the Connecticut action, the differences between the models thereof being in details not pertinent to the issues in the Connecticut or this suit.

13. Notwithstanding the entry of the judgment in the Connecticut action on March 31, 1967, defendant Diapulse Corp. continued to dispose of said Diapulse devices in interstate commerce by sale, lease, gift, grant or other form of disposition through May 1968, misbranded and misrepresented as theretofore.

14. Defendant since said date in May 1968, prior thereto as aforesaid, and subsequently to the date hereof, has been and is now engaged in the business of promoting, selling and introducing and delivering for introduction in

ROSLING, J.

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interstate commerce a device designated as Diapulse, as hereinbefore described, within the meaning of 21 U.S.C. § 321(h) intended for use in the cure, mitigation, treatment and prevention of disease in man and to affect the structure and function of the body of man, and to achieve the therapeutic results without the generation of significant heat.

15. The Diapulse device is claimed to be a pulsed electromagnetic generator which resembles a conventional medical diathermy unit but lacks the energy output of conventional medical diathermy units. It emits its energy in bursts exceeding at such points of emission the output of such conventional unit, and maintains periods of reduced emission or complete lack of emission during intervals between the bursts. The further claim by defendant is that during the period of reduced output the heat generated by the bursts is dissipated, that therapeutic effect is achieved by the penetration of the electromagnetic field of the device into the human body, and that the non-production of heat in consequence of the operation and application of the device to the human body eliminates the possibility of injury to the body from excess heat generated.

The device has, however, been classified as a diathermy unit by the Food and Drug Administration, permitted to operate, and in fact operating on a wave length authorized for comparable diathermy devices, namely, 27.12 megacycles, and

ROSLING, J.

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deriving its therapeutic value, if any, from the introduction of penetrating heat into the human body.

The determination of the Connecticut suit adjudicated the issue respecting the functioning of the Diapulse device in favor of the Food and Drug Administration, and the additional testimony adduced before this court served merely to show that there were some dissenting views of witnesses based on inconclusive results grounded on inadequate data and conjectures drawn therefrom, with a strong suggestion, at least, that some of the witnesses were pseudoexperts who had been financially corrupted by defendant by cash payments or stock interests in defendant or had had their conclusions colored by a heavy investment in the device which proved economically profitable in the practice of the medical or dental professions.

16. In the interstate sale and distribution of the device defendant has utilized a great many items of written, printed and graphic matter which comprise the labeling of the Diapulse device, including leaflets containing directions for use, instructions, warranty and advertising brochures and advertising layouts, reprints of speeches, and reprints or excerpts of reports and published articles concerning the Diapulse device or implying, by association of the name Diapulse with other matter in said documentation, or ambiguously, that there was a relationship between the functioning and value of

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the device and therapeutic claims asserted in the article or report.

17. In the promotion of the interstate sale and distribution of said Diapulse device, the defendant has organized symposia, sponsored meetings and has had exhibits and sales representatives at meetings of physicians, dentists, and other practitioners or alleged practitioners of the healing arts to whom representations were made by or in behalf of the defendant orally and by labeling as to the mode and mechanism of action of the said Diapulse device and its effectiveness in the treatment of disease and in affecting the functions and structure of the human body.

18. The jury, in the Connecticut forfeiture case against the device, reported in addition to its general verdict of misbranding that the Diapulse device there in controversy was misbranded and misrepresented with respect to its therapeutic value in the treatment of 49 diseases, disorders, and conditions and that false or misleading claims had been made in that regard. Pursuant to the charge of the court that it should select only some of the more significant claims as to which interrogatories were propounded by the court and report on them alone as to their falsity and misleading nature, the jury had left 68 interrogatories unanswered.

ROSLING, J.

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The 49 affirmative findings became in consequence res adjudicata and are binding upon this court. Upon close examination, however, of the list of 49 interrogatories thus answered, it is apparent that their scope is so broad that they should be construed as including in their sweep practically all disorders and conditions which afflict the human body or to which it is subject. This conclusion is understandable, for the list is not a scientific one which the Government with the assistance of qualified medical experts prepared, and hence one/ should be free of overlapping or undue vagueness in its glossary

It is rather an aggregation of terms which the defendant had in various contexts included in its sales literature with the obvious intent of pushing its product as a panacea for human ailments. It is for that reason that we find included in the enumeration such all-embracing "puffs" as "safe treatment of the entire patient," "stimulating tissue responses and the natural defense mechanism of the body," "restoring good health," "'perking up' sick, rundown cells of the body with new life and vigor," "reenergizing the human mechanisms,"* and "for giving results where all else has failed. As for huge areas of the body which might be helped, we have "infections," "low back pain," or broader yet, "low back syndrome," "systemic disease," "pelvic inflammatory disease,"

* This includes, no doubt, the pitchman's standbys, constipation and impotence.

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"abdominal and pelvic pain and tenderness," "ulceration," "ear conditions," "severe itching," "peripheral vascular insufficiency," and "adrenal malfunction."

Defendant, however, did nothing of consequence to minimize the effect of its advertising activities for some thirteen months after the entry of the Connecticut judgment on March 31, 1967. It continued its distribution of considerable numbers of its machine misbranded as theretofore. On May 6, 1968, several days after the commencement of this action defendant circulated among its distributors a letter in which, with the use of copious full capitals for emphasis, it dealt with the Connecticut judgment as though defendant's disastrous defeat were no more than a standoff with each side gaining a partial victory and implying that what had not been found to have been misrepresented was an affirmative finding that the device had therapeutic value and that defendant's claims of the manner in which the machine functioned applied with respect to the "unadjudicated" diseases or conditions.

At this trial defendant gave evidence, which the court does not credit, that following May, 1968, it modified its literature by excerpting its "permitted" or "approved" claims from brochures, articles, pamphlets, etc. in which, as originally circulated, it had included these claims with others found by the jury to have been misrepresented. De-

ROSLING, J.

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Defendant's witnesses further testified that it had circulated these bowdlerized versions of its literature among its distributors, and that it had made an attempt, which the court finds was either half-hearted or wholly sham, to gather in from its distributors offending literature as yet uncirculated by the distributors among its medical and dental practitioners. No diligent or rigorous effort appears to have been made by Diapulse to reach the practitioners with the modified literature directly, or to advise them at the very minimum that there was a substantial body of scientific opinion which disagreed with the Diapulse corporation's claims. Worse yet, the present owners of the machine and prospective purchasers were not even informed by the Diapulse company that there had been a suit in Connecticut in which the company had been defeated, and some learned ^{this} for the first time only on the day they testified in this trial.

The patients, who were being subjected to treatment by the device and were paying for the service at so much per treatment, were left by defendant completely in the dark as to the strong possibility that they were paying for something that the device was incapable of providing.

A panoptic view of the proof before this court persuades it (1) that defendant in the sale or other disposition of the device continues to make claims respecting its thera-

ROSLING, J.

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peutic value which were adjudicated false in the Connecticut suit; (2) that defendant has failed and continues to fail to disclose in its literature that there is at least a very substantial body of medical and scientific opinion which is in complete disagreement with the claims made by defendant concerning the therapeutic efficacy of the Diapulse device; (3) that it has not discontinued its substantial sales, leasing, and other disposition of the device in interstate commerce; (4) that no proof on defendant's part is in prospect which may reasonably, when and if introduced, be expected to alter the court's findings as herein set forth; (5) that this court is not a pharmaceutical house with expertise to delineate the outer limits of claims of therapeutic value of the device and the scientific basis for such claims with the exactitude required in a complex judgment unless it is aided by the processing of the device by the Food and Drug Administration; (6) nor is it, until these claims have been thus delineated and evaluated by said body, in a position to give directions for publicity by the defendant which will not only inform the public as to what, if anything, the machine is capable of, but will have the effect of enlightening the public as to the generally held views of science to the contrary of the company's claims and of cancelling out the influence, based on misbranding and misrepresentation, of literature heretofore circulated by defendant.

ROSLING, J.

ORDER 12/8/71

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IV

Order

Inasmuch as the Diapulse device, the propriety of the seizure of which by the Government was adjudicated in the Connecticut action, is substantially identical with the devices and components thereof manufactured by defendant or procured from other manufacturers or contractors by defendant, and disposed of by it to distributors and others in interstate commerce, and said device is presently in the custody of the plaintiff or the Secretary of Health, Education and Welfare, or its division, the Food and Drug Administration,

It is ORDERED that until the entry of a final judgment in this action or until a further order is entered by this court modifying or revoking the preliminary injunction, whichever is earlier, or until the prior release by a duly authorized representative of the Department of Health, Education and Welfare in writing of the Diapulse device seized in the Connecticut action, which release among other matters releases the device for shipment, sale or other disposition, the defendant, Diapulse Corporation of America, and each and all of its officers, agents, servants, employees and representatives, and all and any persons in active concert or participation with it be and they hereby are restrained and enjoined from causing to be shipped, sold, introduced or delivered for

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16.

introduction into interstate commerce, or otherwise disposed of, any of said Diapulse devices, assembled or unassembled; and it is further

ORDERED that said release in writing shall be issued by the Secretary only upon compliance on the part of defendant with the provisions of the order amending the Connecticut judgment, which judgment was filed on March 31, 1967, and which amendatory order, made April 25, 1967, was filed April 26, 1967, with leave to the plaintiff and defendant to move this court at the foot of this order for a modification of the dates for the taking of any of the steps provided in said order of amendment in consequence of the lapse of time since the making of said order, or for any other modification or for the revocation of this order.

Further ORDERED that this preliminary injunction is effective in its restraints immediately except as to the ordinary and usual operations of the company and the disposition of the Diapulse devices in the ordinary course of its business, but is to be fully effective in its restraints on and after December 15, 1971, as to the shipment, sale, offer to sell, or other disposition of said Diapulse devices, assembled or unassembled, in interstate commerce.

U. S. D. J.

DECISION AFTER TRIAL, ROSLING, J. FILED 6/12/72

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK, 4/2/1972
-----x
UNITED STATES OF AMERICA, Plaintiff,

-against-

68-C-391

DIAPULSE CORPORATION OF AMERICA
also known as THE DIAPULSE
MANUFACTURING CORPORATION OF
AMERICA, a corporation,

JUN 9 1972

Defendant.

Appearances:

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Attorneys for Defendant

Milton Bass, Esq.
Of Counsel

ROSLING, J.

Pleadings

Complaint

The action was commenced in this court on April 25, 1968, by the filing of the complaint. It alleges the following:

The action is brought under section 302(a) of the Federal Food, Drug, and Cosmetic Act, ["Act"], 21 U.S.C. § 332(a), which empowers the district courts to restrain violations of section 301(a) and (k) of the Act, 21 U.S.C. § 331(a) and (k). The sole defendant, Diapulse Corporation of America, etc., ["Diapulse" corporation or company] is incorporated in Delaware doing business and having its principal place of business at New Hyde Park, [Nassau County], New York.

Diapulse's business is the promotion, selling, and introducing and delivering for introduction into interstate commerce a device ^{1/} intended for use in the cure, mitigation, treatment and prevention of disease in man. Although resembling ^{2/} a medical diathermy unit it purports to achieve its therapeutic results without generating heat.

In the interstate sale and distribution of the device the Diapulse company utilizes written, printed and graphic matter which comprises the labeling of the device, organizes symposia, sponsors meetings and has exhibits and salesmen at meetings of osteopaths, chiropractors and physicians at which false and misleading representations are made orally and in labeling as to the mechanism of action and effectiveness of the device in the treatment of disease and in affecting the functions and structure of the human body, and the Diapulse company has neither corrected nor repudiated any of such claim

3.
or misrepresentations.

The labeling falsely and misleadingly represents the mechanism of action of the device by claiming the following:

- (a) It treats the human body by pulsed electromagnetic energy without heat.
- (b) It stimulates the reticuloendothelial system ("RES"), thereby stimulating the body's defense and repair mechanisms to speed tissue and healing response.
- (c) It allows heat to dissipate between pulses and therefore has no build up of heat.
- (d) It operates at the cellular level by non-thermal effects.

The labeling further falsely and misleadingly represents the effectiveness of the device both when used alone and as an adjunct to chiropractic, osteopathic, and medical measures in treatment for the following:

A. Stimulating the RES (the body's defense mechanism) and tissue response and changing blood composition as set forth in Appendix A, annexed to the complaint. The Appendix enumerates 59 effects upon the body which the use of the device is represented to have or, in a few instances, to benefit.

B. Infections and systemic infections and diseases including but not limited to 75 conditions and diseases specified in Appendix B.

C. Inflammatory and chronic conditions of which 93 are listed in Appendix C, and other related conditions.

D. Circulatory and metabolic disorders, 53 such diseases or effects in man and 9 in horses being listed.

E. A variety of symptoms which are allegedly benefited by the use of the device of which 23 are enumerated in Appendix E.

The complaint then cites for its res adjudicata effect an in rem proceeding entitled United States v. One Article of Device * * * Diapulse in which the Court of Appeals of this circuit, 389 F.2d 612 on January 30, 1968, affirmed a judgment of the District Court of Connecticut entered in 3/
1967.

Notwithstanding such adjudication defendant, it is further alleged, has not corrected or repudiated any of such claims or representations, but continues to make and use them.

The complaint then charges that defendant is violating Act section 301(a), 21 U.S.C. § 331(a), by causing the introduction and delivery for introduction into interstate

commerce of the device which is misbranded within the meaning of Act section 502(a), 21 U.S.C. § 352(a); further, that the defendant violates Act section 301(k), 21 U.S.C. § 331(k), by causing said device to be so misbranded while it is held for sale after shipment in interstate commerce.

The single cause of action pleaded concludes with allegations that unless defendant is restrained generally it will not discontinue its holding for sale and distribution of the device in interstate commerce and its violation of 21 U.S.C. § 331(a) and (k).

The "Wherefore" claims are longer than the body of
4/
the complaint proper. The capitulations of the relief sought are set forth in the following:

1. A general injunction under 21 U.S.C. § 332(a) against causing the device or any similar device to be introduced or delivered for introduction into interstate commerce in violation of § 331(a) by reason of its being misbranded within the meaning of § 352(a) or (f)(1); and against doing any act which causes the device, etc., to become misbranded while held for sale after shipment in interstate commerce, in violation of § 331(k).

2. An injunction as in subd. (1), supra, against introduction etc., of the device with any claims whatever as

to the device's effectiveness or mode of action in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animal, unless and until defendant should prepare, assemble and submit scientific evidence of its claims and revised labeling to the Food and Drug Administration in conformity with 21 C.F.R. 1.106 and should obtain approval of the matter submitted.

3. A requirement that defendant give notice of the Connecticut court's adjudication to every person known to defendant to have purchased or leased or to be in possession of a Diapulse device, and to its distributors and sales representatives and others.

4. Similar injunctive relief during the pendency of the action.

5. A temporary restraining order.

Answer

The defendant's answer consists of a general denial and three affirmative defenses.

The first defense alleges that the decree of condemnation of the device authorized defendant to relabel it under the supervision of the District Court of Connecticut. Defendant accordingly purports to find that "the instant

complaint is in conflict and inconsistent with the said decree in that it seeks to vary, modify and overrule the Connecticut decree and to interfere with the rights thereunder conferred upon the defendant herein."

The defense alleges further that the Diapulse company's good faith efforts to negotiate with the Food and Drug Administration to comply with the decree of condemnation and relabeling provisions have been arbitrarily rebuffed and should be held in abeyance pending final determination of all appeals from the Connecticut decree of condemnation.^{5/}

The second defense was that the Government had

failed to obtain an adjudication in its favor with respect to 72 [sic] specifically enumerated issues raised by the pleadings and tried in the United States District Court for the District of Connecticut, and now seeks, by the instant action, to relitigate said issues. As such, plaintiff should be barred and estopped from harassing, annoying, and interfering with the lawful pursuit of the defendant's business."

The third defense declared that this court was "without jurisdiction to grant the relief requested by plaintiff in the third paragraph of plaintiff's prayer for relief * * * [a permanent injunction pending receipt from defendant by Food and Drug Administration of evidence and approval by Food and Drug Administration of device as relabeled] * * * because said request for relief is contrary to the decree of condemnation and relabeling in the Connecticut action, and no statutory authority exists for same."^{6/}

The Connecticut SuitThe Libel

On December 16, 1965, the Government filed a libel of information in the United States District Court for the Northern District of Georgia, Atlanta Division, against a Diapulse device and certain literature. The in rem proceeding prayed for seizure and condemnation of the device pursuant to 21 U.S.C. § 301 et seq.

The libel charged that there was at Atlanta, Georgia, in the possession of James E. Tebbel, D.C., doing business as Buckhead Chiropractic Clinic, such device labeled in part by a metal plate affixed to it and inscribed as follows:

"Diapulse Serial No. 1824
Model D * * * Diapulse Manufacturing
Corporation of America New York City
Manufactured by Remington Rand
Division Sperry Rand Corporation * * *"

The device had been shipped prior to December 9, 1963, by the Diapulse corporation to one Drakes in Atlanta, a former representative of the company who delivered it to Tebbel. Additionally, Tebbel had in his possession items of promotional material which had been either mailed to him by Diapulse or received from Drakes in person who had in turn received them from Diapulse.

Misbranding of the device under 21 U.S.C. § 352(a) existed in that its labeling, namely the promotional material accompanying the article, represented and suggested that the article was adequate and effective for treatment of [here follows a lengthy list of diseases and claims of stimulating, enhancing, restoring, reenergizing, increasing, revitalizing, various systems, functions, mechanisms, etc. of the human body] whereas said statements were false and misleading since the article was not adequate and effective for the purposes claimed in the statements.

The article was, accordingly, liable to seizure and condemnation pursuant to 21 U.S.C. § 334 for which relief a prayer was presented.

The answer filed three months later on March 16, 1966 by the Diapulse Corporation of America as claimant pleaded a general denial and asked for a dismissal of the libel.

The action was thereafter at the instance of the Diapulse company transferred to the District Court of
7/
Connecticut.

Trial was begun before Judge Blumenfeld and a jury on February 21, 1967, and continued through March 17, 1967, when the jury returned its verdict for the government libellant. The verdict was in writing and was comprised of two parts: a

general verdict, and what was entitled by the court as a "Special Verdict Form," but which in fact consisted of answers to about 40% of the interrogatories propounded to the jury by the court. (See Fed. R. Civ. P. 49(b) for procedure). Judge Blumenfeld had submitted to the jury 117 diseases, disorders and bodily conditions claimed to have been misrepresented, with instructions by the court that only if the jury found a general verdict against Diapulse of misbranding was it to "turn to" the interrogatories.

"On the three accompanying pages," Judge Blumenfeld had charged, "there have been listed those diseases, disorders and conditions for which the government has alleged that false or misleading claims were made by the labelling. In the event your verdict is for the government, write the word 'Yes' in the blank space before each of those diseases, disorders and conditions for which you find false or misleading claims were made.

"Have each sheet signed by your foreman."

The charge then continued:

"If you should find that one or more of the claims has been proved false or misleading, I will ask that you indicate what those claims are. * * *

* * *

"In the event your verdict is for the Government, if you reach the point where your verdict is for the Government write the word "yes" in the blank space before each of those [items] for which you find, if you so find, that false or misleading claims were made and have each sheet signed by your foreman. * * *

"I am not going to ask you to go through the vast list of 120 [sic] and deliberate upon each one, but go to those -- if you reach them at all, which, in your view, represent the heart of the claims that were made. * * *

* * *

"And still there are too many of them here, 120, to try and manage or even justifiably ask you to pass on each and every one of them. So that is why I say go through the list, but pick out those which you think go to the heart of the claims that are made here and pass only upon those. * * *"

The jury with surprising diligence answered no less than 49 of the 117 interrogatories by the word "Yes," meaning under the instructions of the court that false or misleading claims had been made as to them. The remaining interrogatories were left unanswered.

Later, when an appeal was taken to the Court of Appeals from the judgment of condemnation entered on the verdict as amended ^{8/} that court in its opinion on affirmance gave short shrift to Diapulse's claim "that the judgment is defective in making a general finding in favor of the government when, so it is alleged, the jury issued a special verdict in which it found for the appellant on 72 [sic] of 121 [sic] issues."

The opinion continues:

"Although the form submitted to the jury on which the 121 [sic] issues were listed is headed 'Special Verdict Form,' there was no special verdict in this case. Judge Blumenfeld clearly instructed the jury that if they found one or more false claims of effectiveness, in the labeling, their verdict should be for the government. He then requested that if their verdict should be for the government, they should write 'Yes' in the blank space before each disease, condition, etc. listed on the form as to which they found that false or misleading claims had been made. At another point in the charge, he instructed the jury only to pick out those which they thought went to the heart of the government's claims. His reason in doing this was, as he explained, to help prevent the possibility of compromise among the jurors, and to require instead that they reach agreement on at least one claim before finding for the government. The jury returned a general verdict: 'In this case the jury finds the issues in favor of the libelant and therefore finds that the device is misbranded.' Clearly, the action taken by the court in also requesting the jury to specify some of the claims which it found false or misleading was the submission of special interrogatories, and not a request for a special verdict. Compare Rule 49(a) with Rule 49(b), Federal Rules of Civil Procedure."

The appeal was argued before the Court of Appeals on January 9, 1968, and decided three weeks later on January 30. Before the matter reached the appellate court, however, a number of proceedings following the jury verdict of March 17, 57, had supervened.

Judgment, signed by the clerk of the Connecticut court was made and entered March 31, 1967. It adjudged in

three brief decretal paragraphs that the single article seized was misbranded within the meaning of the Act § 502(a), 21 U.S.C. § 352(a) (1964), ^{9/} and pursuant to Act § 304(a), 21 U.S.C. § 334(a) (Supp. 1967) ^{10/} as amended it was condemned and forfeited to the United States; further, that pursuant to Act § 304(c), 21 U.S.C. § 334(c) (1964), the government should recover costs, fees, storage and such other proper expenses to be taxed; and, finally, that on or before May 8, 1967, the "owner or proper claimant of said device shall show cause why said device shall not be destroyed."

In response to said final decretal provision the Diapulse corporation moved for an order amending the judgment in order to provide for an opportunity to relabel the seized article. Diapulse's petition, brought under Act § 304(d) as amended, 21 U.S.C. § 334(d) (Supp. 1967), prayed that the device should be delivered to it so that it might proceed with the relabeling in conformity with the statute, and the court ^{11/} amended the judgment accordingly. The court's amendments of the judgment are too numerous and detailed for complete summarization at this point. Suffice it to say, however, that the amended judgment directed that the device was to be surrendered to the Diapulse corporation under bond so that it might bring it into compliance and Diapulse was forbidden to

"ship, sell, offer for sale, or otherwise dispose of said article until a duly authorized representative of the Department of Health, Education and Welfare * * * shall in writing have released such article for shipment, sale, or other disposition." If Diapulse "does not avail itself of the opportunity to repossess the condemned article in the manner aforesaid, the United States Marshal for this [Connecticut] district shall retain custody of said article pending the issuance of an Order by this [Connecticut district] court regarding its disposition; * * *."

Judge Blumenfeld additionally directed that he was to retain jurisdiction "to issue such further Decrees and Orders as may be necessary to the proper disposition of this proceeding" and, finally, that the force of the amendatory orders be stayed pending disposition of an appeal if taken.

Diapulse had moved for judgment notwithstanding the verdict, and in the alternative for a new trial. ^{12/} Judge Blumenfeld considered both motions and on May 24, 1967, denied them in an opinion which is reported at 269 F. Supp. 162. The content of the opinion will be considered, as pertinent and required, in the later discussion of the opinion of the Court of Appeals upon affirmance to which we immediately turn. Eight months were to elapse, however, following Judge Blumenfeld's denial of the Diapulse's motions for judgment etc., before the Court of Appeals rendered its decision of affirmance on January 30, 1968. The Court of Appeals found that Diapulse appealed upon five claims on each of which it sustained the holding of Judge Blumenfeld.

The first claim urged by Diapulse was that since there was an honest difference of opinion among medical experts with respect to the issues of effectiveness raised in the libel, there could be no proof that the statements were false in fact and the issues should, therefore, never have been submitted to the jury. The Court of Appeals upheld Judge Blumenfeld's conclusion in ruling on the defendant's motion for judgment n.o.v., that "the evidence demonstrated the existence of scientific standards capable of testing the degrees of effectiveness of a product." Hence, it was proper to submit the issues to the jury.

The second claim based on Judge Blumenfeld's submission of the case to the jury for a general verdict accompanied by answers to interrogatories has already been discussed, (pp. 10 and 10a, supra). Rejecting appellant's contention that a general verdict should not have been rendered, but that the jury should have been required to rule on every one of the 121 [sic] interrogatories, the Court of Appeals noted that the statute in relevant part provides (21 U.S.C. § 352) that "A drug or device shall be deemed to be misbranded -- (a) If its labeling is false or misleading in any particular." (Underscored phrase italicized for emphasis in opinion by Court of Appeals.)

The opinion of the Court of Appeals continues:

"It is argued that because there was a general judgment, and it is not clear what the jury specifically found, appellant will not be able to properly relabel its product. As Judge Blumenfeld said: 'Claimant mistakes the purpose of a court. It is not a pharmaceutical testing house.' Admittedly it would be easier for the claimant in an action such as this to go forward with relabeling its product if the judgment were more specific, but the purpose of the action is simply to condemn the drug, machine, etc. if misbranded (see discussion above), and the action is provided for by statute. The initial determination of the legality of the new labeling is for the administrative body."¹³⁷ [Emphasis supplied.]

The third claim of Diapulse which the Court of Appeals overruled was the argument that Judge Blumenfeld

"changed the issues raised by the label when it instructed the jury that it could find for the government if it found that there was a difference of opinion among medical experts which was not disclosed in the labeling."

Agreeing with Judge Blumenfeld's holding in this regard, the Court of Appeals declared (p. 615 id.):

"But this was not a new issue. 21 U.S.C. § 321(n) reads:

If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested * * * but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect

to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

This has been read broadly, and not improperly, in 21 C.F.R. § 1.3:

The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Cf. Research Laboratories, Inc. v. United States, 167 F.2d 410, 422 (9 Cir. 1948)."

The fourth point Diapulse tendered, but failed to sustain was that

"it was error for the District Court to rule, as a matter of law, that reprints of medical articles constitute 'labeling' within the meaning of the statute. It is argued that an article, journal or book does not become labeling for any drug or medical device which a doctor (or chiropractor) may have in his office. That is no doubt true. See United States v. 24 Bottles 'Sterling, Vinegar, & Honey, etc.' (Balanced Foods, Inc.), 338 F.2d 157 (2 Cir. 1964), cited by appellant. But the essential question is whether the printed material seized with the device supplements or explains the device -- it is the textual relationship, not physical attachment, which is significant. See Kordel v. United States, 335 U.S. 345, 69 S. Ct. 106, 93 L. Ed. 52 (1948); and United States v. Urbuteit, 335 U.S. 355, 69 S. Ct. 112, 93 L. Ed. 61 (1948). Here, the claimant admitted distributing all of the

material seized with the device. A reprint of a 'medical article' need not be treated differently from other printed material alleged to constitute labeling. See *United States v. Hoxsey Cancer Clinic*, 198 F.2d 273 (5 Cir. 1952), cert. denied 344 U.S. 928, 73 S. Ct. 496, 97 L. Ed. 714 (1953).^{14/}

The fifth and last of the points unsuccessfully urged upon Judge Blumenfeld and the Court of Appeals by Diapulse was "that it was error to allow the introduction of evidence, including opinion testimony, about a medical device called 'Therapeutic,' because that device and appellant's device are not the same."

The Court of Appeals ruled that "[o]n the evidence adduced, it was not error to hold that the machines were sufficiently similar to allow introduction of evidence as to 'Therapeutic,' for purposes of evaluating 'Diapulse'.^{15/}"

Certiorari was, as earlier noted, denied by the Supreme Court on June 10, 1968, 392 U.S. 907.

In the meantime, at long last, the lethargic government had bestirred itself and had on April 25, 1968, filed its complaint. It is perfectly plain that had the government filed its suit one year earlier, in 1967, and immediately applied for an injunction comparable in scope to that which prevented the Diapulse corporation from disposing of the single machine forfeited in the Connecticut in rem suit until the device had

been brought into compliance with what the Food and Drug Administration required and it had been released by the Food and Drug Administration, the Diapulse corporation would have been put out of business pending such compliance, provided the rest of the machines it marketed were substantially identical with the forfeited device and the labeling by accompanying literature was substantially the same as was found in the Georgia chiropractor's office.

In the trial ultimately conducted before this court it was practically conceded that the business of Diapulse consisted of the disposition by sale of only two models of the device which except for some minor details not pertinent to the instant issues were substantially identical with the condemned device. Further, the proof was overwhelming that until some time in 1968 no attempt whatsoever had been made to modify the promotional claims Diapulse had been making or implying in marketing its product.

But the slow pace at which the Food and Drug Administration moved against Diapulse gave that company the opportunity to continue its obfuscating tactics and the recklessness to engage in them.

16/

On April 29, 1968, Judge (now Chief Judge) Mishler signed an order to show cause for a preliminary injunction upon the government's application, returnable May 6, 1968.

17/

The show cause order did not, as the temporary restraining order had, track the precise findings of the jury in what was sought to be enjoined.

Instead, the Golden supporting affidavit in Exhibit III annexed thereto purported to establish categories of certain of the affirmative jury findings of misrepresentation and under these headings to list post-verdict representations which Diapulse made concerning the efficacy of its device. Most of these subsequent representations would on simple inspection by non-medical laymen be seen to be a brazen paraphrase of and even literal persistence in the adjudicated misbranding. In the case of other representations medical testimony would have to be supplied to subsume the language thus used after the trial under the adjudicated expressly forbidden categories.

Mr. Golden and the supporting affidavits of the Food and Drug Administration agents Everline and Eastwood earlier referred to, cited a number of specific sales of the device thus misbranded in the post-judgment period.

18/

Both the temporary restraining order and the motion for a preliminary injunction speedily became moot, for on May 2, 1968, Judge Mishler on the consent of defendant issued a preliminary injunction. The order recited:

"[C]ounsel for the respective parties having met and advised the Court that defendant agrees to the issuance of a Preliminary Injunction, as hereinafter set forth, for purposes of effectuating an orderly procedure pending trial and determination of this action and without admitting the allegations of fact or law set forth in the Complaint filed herein; and upon the Consent of the defendant, annexed hereto."

The order followed in his verbis the restraints imposed by the temporary restraining order, rather than those sought by the motion for a preliminary injunction, but extended them for the period pending trial and determination of the action. The government's motion for such injunction returnable May 6, 1968, was declared withdrawn.

The defendant had already laid its plans to evade the restraint even as the order was being signed. These were not long delayed in their disclosure. On May 6, 1968, four days after the injunction order was signed defendant addressed a letter to all its dealers and dealer salesmen throughout the country informing them that

"[a]fter lengthy litigation (which is still pending for consideration before the United States Supreme Court), a judgment was obtained by the Food and Drug Administration to the effect that 49 specifically enumerated claims, out of 121, may not be made for Diapulse units, directly or by implication."

The letter then announced with full bold-faced capitalization that

"72 CLAIMS, HOWEVER, WERE NOT RESOLVED IN FAVOR OF THE FOOD AND DRUG ADMINISTRATION."

The letter next explains with a certain magnanimous condescension that

"On May 1, 1968, without admitting any of the allegations of fact or law as set forth in the complaint, we voluntarily [sic] agreed that an order be entered temporarily prohibiting the shipment or sale of Diapulse units with any of the 49 representations or suggestions, as shown in the attached order." ^{15/} (Emphasis supplied)

Following this, the letter, again reverting with true Madison Avenue salesmanship to full capitalization further emphasized by underscoring, declares:

"THE COURT DOES NOT AFFECT THE COMPANY'S RIGHT TO CONTINUE THE SHIPMENT, SALE AND SERVICING OF DIAPULSE UNITS, EXCEPT FOR THOSE CONDITIONS STATED IN THE 49 CLAIMS."

"DIAPULSE MAY CONTINUE TO BE RECOMMENDED AS ADJUNCTIVE THERAPY IN THE TREATMENT OF THE FOLLOWING CONDITIONS, EXACTLY AS STATED:"

The jury under explicit authority from the court had left 68 interrogatories concerning diseases, disorders and bodily conditions unanswered. Defendant's circular with arrogant effrontery, wholly contrary to the spirit and letter of Judge Blumenfeld's injunction, listed 25 of the 68 diseases as ones for which it was proper, therapeutically and legally, to continue to use its device.

Following the enumeration of these 25 the letter continues:

"To avoid any misunderstanding, and to assure complete compliance with all applicable rulings of the Court with respect to the purposes and uses of Diapulse in the treatment of various diseases, conditions and symptoms, you are to return to us immediately all literature, brochures and treatment charts with the exception of the following, which you may continue to use:

'Experimental Acceleration of Wound Healing,' Bruce M. Cameron, M.D.

'Peripheral Blood Flow Measurements During Application of Pulsed High Frequency Currents,' William James Erdman II, M.D.

'Congressional Record' (261-385-7904)

"Further, no oral statements, representations, or suggestions shall be made which directly or indirectly, indicate, refer, represent, suggest, or create the impression that Diapulse is an adequate and effective treatment for any of the 49 purposes, conditions or diseases listed in the annexed order."20/ (Underscoring in original.)

The letter concludes with advice that the treatment chart and literature are being revised "in accordance with the foregoing" and a bland playing down of what had been adjudicated against it by a pious affirmation that "[a]s always, it has been, and still is the company's policy to comply with all applicable rules and regulations concerning the sale and use of Diapulse." (Emphasis supplied.)

The proof came as no surprise at the instant trial that defendant continued to sell its device after the jury's verdict without making any disclosure to the purchaser that its use-

fulness had been questioned in litigation until misrepresentation and misbranding had been adjudicated.

One further proceeding in the Connecticut suit remains to be mentioned before we turn to a consideration of the pre-trial procedures in the Eastern District action.

On June 10, 1969, exactly one year after the Supreme Court had denied certiorari, Diapulse as claimant filed a motion before Judge Blumenfeld to further amend the 1967 judgment of forfeiture.

The gravamen of the motion was as follows:

Diapulse in a long series of meetings with the Food and Drug Administration both before and after the Connecticut action, "attempted to amicably negotiate relabeling for its article of device, only to be rebuffed at every turn."

Claimant in extensive correspondence with the Food and Drug Administration, submitted to Judge Blumenfeld as exhibits, "has in good faith offered to bring its article of device in compliance with the law, only to receive continued rebuff and nonresponsive answers."

After several paragraphs of like tenor, the motion continues:

"16. That Claimant has relabeled its device so that it is in complete compliance with the law, that is, it claims that its device is adequate and effective for use in treating the following medical conditions:

- (a) Tissue and bone healing;
- (b) Sinusitis;
- (c) Bursitis;
- (d) Arthritis;
- (e) Blood flow to peripheral areas;
(See Exhibit GG)

"17. That the article of device is, in fact, adequate and effective for use in treating the foregoing medical conditions.

"18. That the claim that the article of device is adequate and effective for use in treating the foregoing medical conditions in no way contravenes the findings of the jury and the decision of this Court in the above-entitled action;

"19. That this Court has continuing jurisdiction over this matter and that the terms and conditions regarding the relabeling of the article of device are clearly to be fixed by the Court and not by the Food and Drug Administration, as is more fully noted in the attached 'Points and Authorities in support of Motion.'"

The motion concludes with a "Wherefore" clause praying for an order further amending the judgment by decreeing "that the device has been brought into compliance with the law when labeled as being an adequate and effective treatment for the afore-mentioned medical conditions * * *."

Judge Blumenfeld summarily disposed of the motion on June 24, 1969, by his two-word inscription in the margin on the first page, "Motion Denied." He wrote no opinion.

As for the seized device itself, it has according to proof adduced at trial never left the Clerk's office in Connecticut where it continues to gather dust. The Food and Drug Administration, presumably, has never found anything therapeutic which the machine is capable of as to which truthful representations may be made, nor does it appear that defendant is prepared to make them. Accordingly, it is not surprising that the Food and Drug Administration has not given the requisite consent to the further distribution of the device in interstate commerce.

Pretrial Procedures and
Trial in the Eastern
District of New York

On November 11, 1971, the Court filed an opinion which directed the issuance of a preliminary injunction against the defendant, and on December 8, 1971, a decision constituting its findings of fact and conclusions of law upon such preliminary injunction. Appended to these findings and conclusions was the formal order of the Court providing for such pendente lite injunctive relief.

With a view to enabling defendant to apply within a brief period for a stay pending appeal the Court in such order authorized defendant to continue its ordinary and usual operations and disposition of Diapulse devices in the ordinary course of business, with the proviso that the order was to be fully effective in its restraints on and after December 15, 1971.

Defendant promptly appealed from the interim order and applied to the Court of Appeals for such stay. The stay was granted by order made by the Court of Appeals on
21/
December 13, 1971.

The taking of testimony by this Court had begun on June 7, 1971, and had continued intermittently through November 8th when an order was filed by the Court directing that the hearing on plaintiff's application for a preliminary injunction be consolidated pursuant to Fed. R. Civ. P. 65(a)(2) with the trial of the action for a permanent injunction. Thereafter the trial continued on an almost day-to-day basis and was still in progress when decision comprising the findings and order granting the preliminary injunction was signed on December 8th. These findings were based on the proceedings and testimony through November 29, 1971. What is set forth in the opinion of November 11th, 1971, and these later findings, conclusions and order will not be here repeated, being deemed

incorporated in this opinion by reference.

Inasmuch as the appeal was taken only from the interim injunction order, the ongoing trial the outcome of which would be either a permanent injunction or a final judgment for the defendant went forward notwithstanding such appeal.

However, with 10,000 and more pages of testimony in this Court and in the Connecticut trial and with hundreds of exhibits in both trials to serve as a base for its final determination and with defendant pointlessly using up court time in supplying cumulative testimony through an endless stream of unimportant witnesses, this court on November 29th declared the trial for a permanent injunction closed for the reception of further evidence and set up a schedule for the filing of briefs.

With the stay of the interim injunction lifted by the December 13th order of the Court of Appeals, however, this Court of its own motion on January 6, 1972, reopened the trial to enable the defendant to offer additional testimony which the Court's closing of the evidence on November 29th might have precluded it from presenting. Further sessions of the Court for the hearing of defendant's witnesses were thereafter held on February 1st, 2nd, 3rd, 4th and 10th at which point both
22/
sides rested.

With the conclusion of the testimony nothing was sharpened, nothing was changed, except that the Court no longer felt by its imposed termination of the trial on November 29th it might have shut out something of importance which the defendant had to offer. It was now clear that defendant had had nothing to add.

On March 20, 1972, the Court of Appeals affirmed this court's preliminary injunction, United States v. Diapulse Corporation of America, 457 F.2d 25 (2d Cir. 1972). The opinion added little, if anything, to what had been earlier said by it in its affirmance of the Connecticut district court and what Judge Blumenfeld had written in that court and what this court had enunciated in its grant of the preliminary injunction.

"The Food, Drug, and Cosmetic Act has as its purpose," the Court of Appeals declared,

"the protection of the public from products not proven to be safe and effective for their alleged uses and the safeguarding of the public health by enforcement of certain standards of purity and effectiveness. The reach of the Act is broad and the provisions, touching the public interest in a direct way, are to be given a liberal construction."

At a later point: "No specific or immediate showing of the precise way in which violation of the law will result in public harm is required."

As for exercise of judicial discretion in issuing and framing the terms of an injunction, the Court of Appeals declared:

"The injunction may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur."

In answer to the contention that the injunction was impermissible as calculated to put defendant out of business, the opinion's acerb comment was an excerpt from an earlier case that there "'can [be] no vested interest in a business activity found to be illegal.'"

In summation the Court of Appeals had this to say:

"The device had been found to be generally misbranded, in violation of the statute, and in addition, a jury of laymen had found 49 specific claims to be false or misleading. Yet the company continued its brazen advertising scheme, failing to inform its buyers and lessors of the litigation or of the dispute in medical circles about the machine's efficacy. It did not prove the machine's effectiveness or relabel it to the FDA's satisfaction. The company's persistence in marketing the device makes it highly likely that the prohibited activity will cease only on the issuance of a blanket prohibition on shipment."

The argument had been advanced by appellant that this Court's requirement that the FDA approve the labeling as a condition for lifting the injunction imposed upon defendant an illegal "pre-clearance" restriction before the

device could be manufactured and shipped. To answer the Court of Appeals wrote:

"The circumstances of this litigation make analogy to pre-clearance less than persuasive. Diapulse is not attempting to market the machine for the first time; on the contrary, a machine differing only in detail from present models has been condemned because the labeling was false and misleading. Corrective measures are required before the machine can be shipped in commerce. The court below found, following the order in the Connecticut action, that the FDA, the administrative agency charged with implementation of the statute which the company was found to be violating, was the best qualified to assess and formulate, with the company, labeling that is not false or misleading. The court itself is not expert on the medical and scientific issues which must be explored in order to produce accurate labeling; the assignment of that function to the FDA is sensible and proper. Cf. United States v. Allan Drug Co., 357 F.2d 713 (10th Cir. 1966). The order does not leave the company in doubt about what acts are prohibited or the methods by which it can proceed to correct its violations."

Finally, the opinion gave to this Court the recognition trial courts sitting without a jury are endlessly accorded of having the primary authority "to judge of the credibility of the witnesses."

Nothing that followed the taking of the appeal has affected the mountain of testimony and findings that preceded, nor except for some brief observations will this Court undertake to add to what it has already written nor to what the Court of Appeals wrote in affirmance.

Defendant has sought to overwhelm the several courts which have toilsomely dealt with its claims and the expertise of its witnesses. To argue detail with defendant at this point is both impossible and uncalled for. To do so would, in fact, drop the government in the semantic pit which the defendant has planned and dug for it. The only sensible rejoinder is that having been adjudged guilty of substantial misbranding, the defendant must now affirmatively establish what, if anything, its device is good for.

The procedure whereby a district court defers to a government agency with special skills and facilities, permitting it to make factual determinations in limited areas, and, when made, to fit them into the Court's broader rulings ^{23/} is not unusual. The Court of Appeals has approved such procedure.

The use, moreover, by defendant of its advertising matter both before and after the roof caved in upon it in Connecticut evince at best an attempt to evade the effect of the adverse adjudication, and at worst a brazen -- (the word is that used by the Court of Appeals on its affirmance of this court, not this Court's) -- disregard of its obligations to the public in marketing a device which may have some medical value or, as is likely, represents no less than sheer quackery.

24/

The appended footnote indicates how the type of advertising, now generally ascribed to "Madison Avenue" can mislead while pretending innocent compliance with judicial restraints.

Defendant's attempt to present the nondescript host of witnesses it called, some medical, some lay and some of less respectable professions, as outstanding research specialists is preposterous. The lay, half-educated individuals who administer the affairs of the defendant and of which one, Ross, has the chief proprietary interest, are on the showing made before this court, somewhat less than completely interested in pure scientific research as applied to the sole product which Diapulse purveys. If this were a negligence action with medical "experts" hired and feed by both sides, espousing diametrically opposed views on what does and does not ail a plaintiff -- an antilogy judicially often remarked upon -- the court would perforce shrug the matter off, leaving to the all-wise jury the assessment of medical credibility.

But when, as here, a swarm of witnesses have testified, and cross-questioning of some has elicited relationships and pecuniary involvements with the defendant which are incompatible with that complete material neutrality which is the hallmark of a medical research man and his findings, one must infer that defendant's case as a whole is at the very least suspect.

51A

One final observation is in order. The proof in this trial running to many thousands of pages and based on months of testimony was received by the Court more liberally than would have been the case had the Court known in advance the full scope of what it knew by the time the trial concluded. *Res adjudicata* was operative as to most of the issues when the Connecticut forfeiture was first adjudged. Only some major scientific discovery subsequently transpiring could have required the reopening of the issues, and even as to that the Court would have been constrained to assume that the FDA would take that into account in its consideration of any usefulness the device might have. But the fact is that nothing which has been shown by defendant upon the trial has in the slightest degree served to strengthen the position which it maintained in Connecticut with such notable lack of success.

It is the Court's conclusion that the temporary injunction issued by it on December 8, 1971, should now be made permanent.

The foregoing and the matters incorporated therein by reference constitute the findings of fact and conclusions of law of the Court. The government has submitted proposed findings of fact and conclusions of law. The defendant has not done so.

Each party shall have until June 26, 1972, to serve upon the adverse party proposed amendments to these findings and conclusions and a proposed judgment for signature by the Court, making the preliminary injunction permanent, and file the same with the Court on or before June 30, 1972, thereafter.

Henry Rosling
H. Rosling
D. J.

FOOTNOTES

1/ See Act § 201(h), 21 U.S.C. § 321(h) for definition of term "device."

2/ It is so classified by the Food and Drug Administra-
tion, ["FDA"].

3/ Judgment of forfeiture of a single machine was signed by District Court Judge Blumenfeld on March 31, 1967, after a verdict by a jury which rendered a general verdict of misbranding and answered affirmatively specific interrogatories as to misrepresentation in 49 instances as to diseases and conditions. No answer was made by the jury as to the remaining 68 diseases and conditions submitted to it. Judge Blumenfeld instructed the jury that if it returned a verdict of misbranding it was not "to go through the vast list of 120 [sic] and deliberate upon each one, but go to those -- if you reach them at all, which, in your view, represent the heart of the claims that were made * * * and pass only upon those * * *."

Following entry of judgment Judge Blumenfeld upon application of Diapulse entered an order on April 25, 1967, giving it an opportunity to relabel the device to bring it into compliance with the law, subject to and evidenced by the approval of the FDA pursuant to Act § 304(d), 21 U.S.C. § 334(d) (Supp. 1965). Such approval, as noted, p. 25, supra, has not been obtained. Thereafter the Diapulse corporation moved for judgment notwithstanding the verdict and for a new trial. Judge Blumenfeld denied the motion, 269 F. Supp. 162, decided May 24, 1967.

The Connecticut case was in this posture when the appeal to the 2d Circuit Court of Appeals was taken by the Diapulse corporation. After the affirmance by that court on January 30, 1968, 389 F.2d 612, the instant suit was begun in the Eastern District of New York by the filing of the complaint on April 25, 1968. Shortly thereafter on June 10, 1968, the Supreme Court denied certiorari, 392 U.S. 907, 88 S. Ct. 2059.

4/ i.e. without the appendices.

5/ As will shortly appear, the Court of Appeals had already affirmed the Connecticut district court's determination on January 30, 1968, several months before suit was started in this court and all that remained was for the Supreme Court to deny certiorari which it did on June 10, 1968, less than four weeks after the answer was filed herein.

6/ The second and third defenses are frivolous. The first defense is not far behind. See in particular footnote 2.

7/ Procedure requiring such removal for trial to "a" district of reasonable proximity to the claimant's principal place of business" unless the parties otherwise stipulate is provided for in Act § 304(a), 21 U.S.C. § 334(a), as then and presently in force.

8/ United States v. An Article of Device * * * Diapulse Manufacturing Corporation of America, 389 F.2d 612 (2d Cir. 1968).

9/ "A drug or device shall be deemed to be misbranded -- (a) If its labeling is false or misleading in any particular."

10/ "§ 334. Seizure -- Grounds and jurisdiction

(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within jurisdiction of which the article is found: * * *."

11/ Act § 304(d), 21 U.S.C. § 334(d) as then applicable and currently in force reads:

Disposition of goods after decree of condemnation

"(d) (1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: Provided, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond."

12/ Pursuant to Fed. R. Civ. P. 50(b) and 59.

13/ Judge Blumenfeld's opinion contains a comment which illuminates the possibilities open to a cunning purveyor of misrepresented worthless, or worse, pseudo-therapeutic devices, of endlessly delaying and thus defeating the government's efforts to put a merited quietus to his activities. Judge Blumenfeld writes (p.168 *id.*):

"Thus, the interrogatories were designed to protect the claimant who is now objecting. A second benefit from the interrogatories is the protection they give to both parties. The bases of the jury's verdict, thus particularized, permit the accurate review of both the sufficiency of the evidence and the propriety of its admission.

"But to secure these advantages, it was not necessary to require either a 'yes' or a 'no' to each claim. This would have required the

jury to deliberate for days, perhaps even longer. The temptation would be great for purveyors of misbranded products to make literally thousands of spurious claims; of necessity, the Government in seeking condemnation would not realistically be able to present evidence on so many claims, or if it did, the jury would be unlikely to remember all of them. Since the burden of proof rests on the Government, e.g., United States v. 47 Bottles, *supra*, 200 F. Supp. 1; United States v. 11-1/4 Dozen Packages, 40 F. Supp. 203 (W.D.N.Y. 1941), a jury would perforce have to find for the claimant on those claims which it could not remember, or on which the Government, because of the sheer mass of false claims, had not been able to present evidence. Thus, at the cost of sacrificing one device or sample of a product because only a few of the misbranding claims were found proved, a claimant would have obtained a judgment constituting a bar to any future action against all the rest of its devices on the remaining claims, spurious though they may be.

"The jury was not required to answer all of the interrogatories."

14/ This holding of the Court of Appeals was consistently ignored by Diapulse's counsel in the trial before this court, with iterated disclaimers of the labeling effect of literature which it continued with reckless disregard of content and no or inadequate warning to the recipients to sponsor and circulate as a promotional ambience for the sale of its device.

15/ Similar testimony was received by this Court in the early stages of the trial when it was endeavoring to familiarize itself with the scope of the proof it was to receive before it had had an opportunity, since availed of, to read the 2,000 plus pages of Connecticut trial record and to assess the res adjudicata effect of the judgment rendered by that court.

16/ Misbranding carries with it criminal penalties of fine and imprisonment under 21 U.S.C. § 333 and, if an injunction against disposition were granted, violation of the injunction would, of course, expose the contemnor to civil and criminal punishment for the contempt.

DECISION AFTER TRIAL, ROSLING, J., FILED 6/12/72

39.

17/ Judge Mishler had on the same day signed a temporary restraining order against the Diapulse corporation enjoining it from introducing into interstate commerce any similar device, assembled or unassembled, bearing or accompanied by leaflets, brochures, etc. that said articles are an adequate and effective treatment for the 49 diseases, disorders and bodily conditions as to which the Connecticut jury had reported affirmatively that there had been misrepresentation.

The temporary restraining order was directed to expire by May 9, 1968, unless otherwise ordered by the Court and hearing on the application by the government for a preliminary injunction was set down for May 6, 1968.

18/ It appears that the same affidavits were submitted in support of the temporary restraining order (Golden and Everline, sworn to April 24, 1968, and Eastwood, April 16, 1968) as were presented as a basis for the preliminary injunction.

In opposition to the temporary restraining order defendant submitted only the single affidavit of its president, Jesse Ross. It is clear that the thrust of the government's applications for a temporary restraining order and an interim injunction was the claim that after the entry of judgment in Connecticut on March 31, 1967, inspectors of the FDA had found "samples of the device and accompanying labeling making the same claims as those adjudged false in the seizure action to have been shipped by the defendant to various distributors and purchasers across the country," (Carl Golden affidavit, p. 2) and that as recently before the applications for injunctive relief as April 5, 1968, the manufacturing and distribution operations of the company were being expanded.

While technically the Connecticut condemnation and restraint was directly limited to the single machine which had been seized, defendant plainly understood that the Diapulse company and its chief officers, personally, were amenable to criminal sanctions should Diapulse continue to sell or lease its product with similar labeling.

It was no doubt fear of such penalization which prompted Ross in his affidavit to limit his opposition to a denial of "the impression" which the government sought to create "that the defendant shipped the machines to Illinois, Portland, Oregon and Wichita, Kansas, accompanied by literature making some or all of the 49 claims as to which the jury in its special verdict answered 'yes'."

DECISION AFTER TRIAL, C., FILED 6/12/72 ROSLING, J.

40.

19/ Note the complete absence of any suggestion that the adjudication was an adverse one of sweeping misrepresentation by Diapulse of the therapeutic efficacy of its device, to say nothing of the criminal and contempt sanctions to which the further distribution of the misbranded device implicitly exposed the company and the individuals who were its confederates in wrongdoing. Nor was the preliminary injunction order circulated in its complete form. The part of the order distributed with the letter omits all the pejorative introductory recitals, including the judgment of misbranding filed in Connecticut March 31, 1967.

20/ Note how shrewdly the author of the letter converts a complete judicial restraint by reason of major misrepresentations, possibly tainted with fraud, into an implied approval by the court that the device is beneficial in the treatment of many diseases. Note also the suggestion that no more is involved in the government's intransigent prosecution of a major offender than a friendly disagreement with a government agency as to the effect of "applicable rulings."

21/ The appellate court's order provided for an expedited appeal.

22/ Although defense counsel had urged vigorously upon the Court before the hearings were scheduled that defendant had a host of professional witnesses to be called whose testimony was crucial, the host never materialized and the volume of testimony for which full days of court time were scheduled speedily dwindled into a trickle of generalizations and repetitions of unimportant clinical observations by equally unimportant witnesses. It appeared to the Court when defense counsel announced on February 10th that he rested, that it was with a sense of relief that he did so.

23/ In Re Scranton Corp., 235 F. Supp. 770, 774, 775 (M.D. Pa. 1964). Cf. Best v. Humboldt Placer Mining Co., 371 U.S. 334, 83 S. Ct. 379 (1963); Thompson v. Magnolia Petroleum Co., 309 U.S. 478, 60 S. Ct. 628 (1940).

24/ A half century ago Dr. Royal S. Copeland, a physician who was also senator from the State of New York conducted an innocuous and indeed, instructive radio program in which he

spoke briefly on medical topics in orthodox fashion. The Court recalls tuning in one day and hearing the good doctor speak of cancer of the stomach in modulated tones and with content wholly sincere and unexceptionable. Moments after he had concluded, however, the quack of the day could be heard broadcasting, in the program immediately following, the pitch for his particular health food. This, he blatantly proclaimed, if diligently ingested would by dietary mumbo jumbo shoo away the nasty carcinoma. The collocation of programs may have been an innocent one, but their synergistic effect on the troubled listener was manifest.

This is a crude illustration of how one may advertise without seeming to. Where, as here, defendant asserts that it can "plug" as therapeutic what has not been literally and expressly forbidden, it is clear that if it is to be permitted to sell its device again, it should concomitantly be well supervised and for an extended period be required to publicize the adverse findings of the courts as to its product and its own contrition at the misinformation it has diffused as part of its merchandising in the past.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FILED
in Clerk's Office
U.S. District Court E.D. N.Y.

UNITED STATES OF AMERICA,
Plaintiff,

Civil No. 68-C-391

v.

DIAPULSE CORPORATION OF
AMERICA, also known as
THE DIAPULSE MANUFACTURING
CORPORATION OF AMERICA,
a corporation,

PERMANENT INJUNCTION

Defendant.

In accordance with the Findings of Fact and Conclusions of Law
heretofore made by this Court on December 8, 1971, and June 9, 1972,
after trial, it is

ORDERED, ADJUDGED, AND DECREED as follows:

I.

This Court has jurisdiction over the subject matter herein and
parties hereto, and the Complaint for Injunction states a valid cause of
action against the defendant under the Federal Food, Drug, and Cosmetic
Act.

II.

The Diapulse device referred to in this Injunction is an electro-
magnetic generator similar to conventional medical diathermy but differing
from it in that its output is pulsed and in that it lacks the energy output
of conventional medical diathermy. The Diapulse is classified as a dia-
thermy device under the regulations of the Federal Communications Commission
and operates on the 27.12 megacycle wave length authorized by the FCC for
diathermy devices.

III.

The defendant, Diapulse Corporation of America, a corporation,
and each and all of its officers, agents, servants, employees, and repre-
sentatives, and all and any persons in active concert or participation

with it be and they are hereby permanently enjoined under 21 U.S.C. 332(a) from violating 21 U.S.C. 331(a) and (k) by directly or indirectly causing any of the following acts with respect to articles of device known as Diapulse, or any similar articles of device, since such acts would result in the device being misbranded within the meaning of 21 U.S.C. 352(a) and (f)(1):

A. Causing to be introduced or delivered for introduction into interstate commerce any of said articles in whole or in part, assembled or unassembled, which:

1. Bears or is accompanied by any item of written, printed, and graphic matter, such as leaflets containing directions for use, leaflets containing instructions, and warranty brochures, advertising brochures, advertising lay-outs, reprints of speeches, and reprints of published articles, which contain statements and representations that directly or indirectly infer, represent, suggest, or create the impression that said articles are adequate and effective in the cure, mitigation, treatment, or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals.

2. Fails to state in its labeling all of the purposes, conditions, and diseases for which said articles are intended for use, and for which said articles are represented by any means by said defendant to prospective dealers, purchasers, renters or lessees; and which also fails to state in its labeling the effects of the device on the human body, its mode or mechanism of action; route, methods, frequency and duration of administration; and any relevant hazards, contraindications, side effects and precautions necessary for safe use.

3. Is intended for delivery to any person whom said defendant has good cause to believe does or will represent by any means to prospective dealers, purchasers, renters, or lessees of said articles that said articles are adequate and effective for the cure, mitigation, treatment or prevention of disease in man or other animals, or to affect the structure or any func-

tion of the body of man or other animals.

B. Causing any act to be done with respect to any of said articles while any of said articles are held for sale after shipment in interstate commerce, which act results in any of such articles being misbranded in any of the ways specified in parts 1, 2, and 3 of paragraph A above.

IV.

The defendant, Diapulse Corporation of America, a corporation, and each and all of its officers, agents, servants, employees, and representatives and all and any persons in active concert or participation with it be and they are hereby permanently enjoined from causing to be shipped, sold, leased, introduced or delivered for introduction into interstate commerce, or otherwise disposed of, any of said articles of device known as Diapulse, or any similar articles of device, in whole or in part, assembled or unassembled, unless and until the said defendant assembles the scientific evidence on which labeling of the device is to be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug, and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106, and the defendant submits such evidence and labeling to the Food and Drug Administration and obtains approval thereof in writing.

V.

The defendant, within 30 days from the date of entry of this decree, shall give written notice by certified mail, return receipt requested, of the provisions of the judgment of this Court by sending a copy of the Court's memorandum decision of June 9, 1972, and a copy of this Permanent Injunction, to each and every person known to the defendant to have purchased, leased or have in his possession a Diapulse device, and to the officers, agents, and employees of the defendant and to each and every person who has been or is a distributor of the Diapulse device or a sales representative for said device, and to all persons now in active concert or participation with said defendant, assisting or participating in the sale,

PERMANENT INJUNCTION -- 7/18/72

promotion, or manufacture of said device, and defendant within 40 days from the date of entry of this Permanent Injunction, shall advise plaintiff of the name and address of each person so notified, and defendant shall give said notice of the provisions of this Court's judgment to all persons in the future in active concert or participation with said defendant, assisting and participating in the sale, promotion, or manufacture of said device or any similar device.

VI.

The Court retains jurisdiction of this case for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate.

VII.

The plaintiff, United States of America, shall recover from defendant the costs of this action, to be taxed by the Clerk of the Court.

DATED: Brooklyn, New York

July 15, 1972.

/s/ George Rosling
UNITED STATES DISTRICT JUDGE

MEMORANDUM, DOOLING, J., INCORPORATING
FINDINGS OF FACT AND ORDER, 5/7/74

U. S. DISTRICT COURT

MAY 7 1974

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORKTIME AM
73MCR-973.....

UNITED STATES OF AMERICA,

68 C 391

- against -

DIAPULSE CORPORATION OF
AMERICA, et al., : MEMORANDUM
: INCORPORATING FINDINGS
: of FACT and ORDER

Defendants. :

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Appearances:

CYRIL HYMAN, Esq., and FORREST PATTERSON, Esq.,
(EDWARD JOHN BOYD V., Esq., United States Attorney,
of Counsel)

For the Government

COPAL MINTZ, Esq.
For Defendants

DOOLING, D. J.

The present proceeding was initiated by an Order to Show Cause of August 1, 1973 (filed August 3, 1973) why Diapulse Corporation of America, DCA Leasing Corp., Jesse Ross and Bernard O. Siler, should not be punished for contempt for disobeying the preliminary injunction in the civil action (which had been affirmed by the Court of Appeals) by sending from New Hyde Park to Las Vegas, consigned to Jesse Ross, President of Diapulse and of DCA, an article of device labeled P/EmF and for violating the final injunction entered July 15, 1972, by sending to Robert Zimmerman of Zimmerman Medical Equipment, Inc., and Doctors Coordinate, Ltd., on July 19, and on July 25, from New Hyde Park to Pecatonica, Illinois, P/EmF Modification Kits; by sending to Melvin C. Appel of Professional Electronics, Inc., in Portland, Oregon from New Hyde Park, such a P/EmF

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Modification Kit; by sending to Gilbert Cook (Gil Cook X-Ray Co.) in Tampa, Florida such a P/EmF Modification Kit; and by sending on or about August 2, 1972 to Joseph R. Groves of Medical Equipment Company in Roanoke, Virginia from New Hyde Park, several P/EmF Modification Kits; and by sending literature respecting Diapulse from New Hyde Park to Campbell Soup Co. in Chicago, Illinois, while Campbell Soup had in its possession a Diapulse article of device.

There is no genuine controversy about what the defendant Diapulse and the individual defendants and DCA did. The P/EmF labeled device was, of course, sent from New Hyde Park to Las Vegas for display at a convention or conference of the American Physical Therapy Association; it was sent after the preliminary injunction had been affirmed in the early part of June 1972, and it was returned to New Hyde Park after the convention ended in June 1972, both shipments being made while the preliminary injunction was in full force and effect and before the final injunction had been entered. The preliminary injunction forbade the introduction into Interstate Commerce of "any of said Diapulse devices, assembled or un-assembled" and "Diapulse Devices" are inferentially defined as those "substantially identical" with the Diapulse Device, the propriety of the seizure of which by the government was adjudicated in the earlier Connecticut action. See 269 F.Supp. 162, 339 F.2d 612, certiorari denied, 392 U.S. 907.

After the issuance of the final injunction defendant

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DCA Leasing Corp., a wholly owned subsidiary of Diapulse, having common officers and control, shipped 297 of the P/EmF Modification Kits to purchasers within the United States. Fifty-five of these were shipped to Ross Medical Electronics in Kensington, Connecticut; 41 to Medical Aid Sales Company in Brooklyn, New York; 36 to Doctors Coordinates in Pecatonica, Illinois (Robert Zimmerman); 30 to Robert Ford in El Monte, California; 24 to Melvin Appel (Professional Electronics, Inc.) in Portland, Oregon, and 20 to Gilbert Cook at Gil Cook X-ray Company in Tampa, Florida, with smaller numbers being shipped to buyers in other locations. In addition, the Diapulse Corp. has shipped to foreign countries since the date of entry of the final injunction, Diapulse equipment of the kind sold in the United States before the litigation in Connecticut and in New York.

The principal models of Diapulse equipment that had been manufactured and distributed before the litigation were identified as D-101, of which 2400 to 2500 had been made and sold, for the most part in the United States, and the D-102, 2000 to 2500 of which were made and sold principally in the United States. Roughly 700 of Diapulse devices in all have been made here and sold abroad.

The Diapulse device condemned in the Connecticut case and dealt with in the temporary and permanent injunctions in this Court is classified for Federal Communications Commission type-approval purposes with diathermy devices. It

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is a short wave, high frequency, electromagnetic device operating at 27.12 megahertz, and is operable from a standard 117 volt 60 cycle AC 5-1/2 ampere electric current, the kind delivered by American utilities to residential and commercial properties.

Characteristic of the Diapulse device is that its electromagnetic energy is pulsed, that is, delivered in very short bursts of electrical energy separated by rather wide spaces in which no electromagnetic energy is flowing. The pulse width or pulse duration in the Diapulse device was 65 millionths of a second. That was an unalterable feature of the equipment: that at all pulse frequencies the length of the individual pulse was the same 65 millionths of a second. The Diapulse device had six pulse frequency settings, that is, 80 pulses per second, 160 pulses per second and then 300, 400, 500 and 600 pulses per second. Simple multiplication demonstrates that the effect of that is that when 80 pulses per second were used, each pulse being 65 millionths of a second in duration, the current was actually flowing approximately one-half of 1% of the time, that is, 0.52%. In consequence, at 160 pulses per second the current would be flowing about 1% of the time, at 300 pulses a second the current would be flowing 1.9% of the time and so on up to 600 pulses per second when the current would be flowing for 3.9% of the time.

In the Diapulse device of the past, peak power expressed in watts during each short burst of power was 975

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watts. There were on the Diapulse of the past six power settings; on the machine's control panel power settings were treated as "penetration" levels, since it was the teaching of the authors of the machine that peak power determined the penetration of the electromagnetic effect into the body. The six peak power settings were at 293 watts, 390 watts, 488 watts, 585 watts, 780 watts and 975 watts. Since, as noted, the device delivered current for as little as one-half of 1% of the time at 80 pulses per second and at 3.9% of the time at 600 pulses a second, the average power output was radically lower than the peak power. Indeed, at the lowest penetration setting and the lowest pulse frequency setting the average watts of output power was 1.52 watts; at the highest penetration and pulse rate settings the output was 38 watts.

The electromagnetic energy emanating from the device was delivered to the person under treatment through an applicator or treatment head roughly the shape of a kettle drum; the operative part of the treatment head was an induction coil comprising a number of concentric turns of heavy, banded conductor. The treatment head functioned by inducing a flow of current in the tissues at depth; that is, the device operated by induction. The Diapulse device inevitably produced heat at depth, but not in any therapeutically significant amount; indeed, the only indication is that at its highest settings at the end of 20 minutes it could result in an increase in local tissue temperature from normal to $101-1/2^{\circ}\text{F}$.

The Diapulse device was over the years presented aggressively as an electromagnetic therapeutic device. It was explicitly, not for heat therapy. On the contrary, it was for electromagnetic therapy, and was originally presented as essentially athermal, and it was only reluctantly conceded that it produced some local increase in temperature within the human tissue at depth, the extent of any such increase in temperature being a function of the capacity of the circulation of body fluids in the tissues to attemperate the inevitable evolution of heat by the flow of electromagnetic energy in the tissue. Defendants have not accepted the view that any physiological effects claimed for Diapulse treatment are due to the mild elevation in temperature inseparable from any application of electromagnetic energy to human tissue through a machine with the characteristics of the Diapulse. Defendant Ross, speaking for the companies and himself, was explicit that the interest of the group is not in diathermy nor in diathermic therapy as such, nor, indeed, in diathermic modalities. The insistence of defendant Ross and the corporations for which he speaks continues to be on the validity and utility of the use of pulsed short-wave, high peak-power, electromagnetic induction as a therapeutic agent, and their long-term interest is in the manufacture or assembly and distribution of medical modalities capable of administering such therapy.

Defendants have continued to encourage and, to an extent not disclosed, to lend support to a large number of research projects, clinical and other, here and abroad; the evidence requires the conclusion that all of these, without exception, are devoted to exploring the physiological effect and therapeutic utility of pulsed electromagnetic therapy of the kind which the Diapulse devices D-101 and D-102 are capable of supplying and are limited to supplying, and that there are no research projects of any kind devoted to diathermic heat therapy which have the support or sponsorship or claim the interest of defendants.

It appears that the Diapulse device as recently as at the time of the Las Vegas convention referred to above, was offered for sale in the range of \$2,200.00 for each Diapulse modality.

Critically important findings were made by Judge Rosling at the time of the issuance of the preliminary injunction under date of December 18, 1971, and these findings were the following:

"15. The Diapulse device is claimed to be a pulsed electromagnetic generator which resembles a conventional medical diathermy unit but lacks the energy output of conventional medical diathermy units. It emits its energy in bursts exceeding at such points of emission the output of such conventional unit, and maintains periods of reduced emission or complete lack of emission during intervals between the bursts. The further claim by defendant is that during the period of reduced output the heat generated by the bursts is dissipated, that therapeutic effect is achieved by the penetration

"of the electromagnetic field of the device into the human body, and that the non-production of heat in consequence of the operation and application of the device to the human body eliminates the possibility of injury to the body from excess heat generated.

The device, has, however, been classified as a diathermy unit by the Food and Drug Administration, permitted to operate, and in fact operating on a wave length authorized for comparable diathermy devices, namely, 27.12 megacycles, and deriving its therapeutic value, if any, from the introduction of penetrating heat into the human body.

The determination of the Connecticut suit adjudicated the issue respecting the functioning of the Diapulse device in favor of the Food and Drug Administration, and the additional testimony adduced before this court served merely to show that there were some dissenting views of witnesses based on inconclusive results grounded on inadequate data and conjectures drawn therefrom, with a strong suggestion, at least, that some of the witnesses were pseudoexperts who had been financially corrupted by defendant by cash payments or stock interests in defendant or had had their conclusions colored by a heavy investment in the device which proved economically profitable in the practice of the medical or dental professions.

16. In the inter-state sale and distribution of the device defendant has utilized a great many items of written, printed and graphic matter which comprise the labeling of the Diapulse device, including leaflets containing directions for use, instructions, warranty and advertising brochures and advertising layouts, reprints of speeches, and reprints or excerpts of reports and published articles concerning the Diapulse device or implying, by association of the name Diapulse with other matter in said documentation, or ambiguously, that there was a relationship

"between the functioning and value of the device and therapeutic claims asserted in the article or report.

17. In the promotion of the inter-state sale and distribution of said Diapulse device, the defendant has organized symposia, sponsored meetings and has had exhibits and sales representatives at meetings of physicians, dentists, and other practitioners or alleged practitioners of the healing arts to whom representations were made by or in behalf of the defendant orally and by labeling as to the mode and mechanism of action of the said Diapulse device and its effectiveness in the treatment of disease and in affecting the functions and structure of the human body.

18. The jury, in the Connecticut forfeiture case against the device, reported in addition to its general verdict of misbranding that the Diapulse device there in controversy was misbranded and misrepresented with respect to its therapeutic value in the treatment of 49 diseases, disorders, and conditions and that false or misleading claims had been made in that regard. Pursuant to the charge of the court that it should select only some of the more significant claims as to which interrogatories were propounded by the court and report on them alone as to their falsity and misleading nature, the jury had left 68 interrogatories unanswered.

The 49 affirmative findings became in consequence res adjudicata and are binding upon this court. Upon close examination, however, of the list of 49 interrogatories thus answered, it is apparent that their scope is so broad that they should be construed as including in their sweep practically all disorders and conditions which afflict the human body or to which it is subject. This conclusion is understandable, for the list is not a scientific one which the Government with the assistance of qualified medical experts prepared, and hence one which should be free of overlapping or undue vagueness in its glossary."

The findings made in the decision of December 8, 1971, were reincorporated in the Court's decision granting the final injunction dated June 9, 1972, and filed June 12, 1972. One further finding made in the preliminary injunction decision and carried forward to the date of the final injunction is the following:

"A panoptic view of the proof before this court persuades it (1) that defendant in the sale or other disposition of the device continues to make claims respecting its therapeutic value which were adjudicated false in the Connecticut suit; (2) that defendant has failed and continues to fail to disclose in its literature that there is at least a very substantial body of medical and scientific opinion which is in complete disagreement with the claims made by defendant concerning the therapeutic efficacy of the Diapulse device; (3) that it has not discontinued its substantial sales, leasing, and other disposition of the device in interstate commerce; (4) that no proof on defendant's part is in prospect which may reasonably, when and if introduced, be expected to alter the court's findings as herein set forth; (5) that this court is not a pharmaceutical house with expertise to delineate the outer limits of claims of therapeutic value of the device and the scientific basis for such claims with the exactitude required in a complex judgment unless it is aided by the processing of the device by the Food and Drug Administration; (6) nor is it, until these claims have been thus delineated and evaluated by said body, in a position to give directions for publicity by the defendant which will not only inform the public as to what, if anything, the machine is capable of, but will have the effect of enlightening the public as to the generally held views of science to the contrary of the company's claims and of cancelling out the influence, based on misbranding and misrepresentation, of literature heretofore circulated by defendant."

The circuitry of the Diapulse D-101 and Diapulse D-102 is shown in Exhibit 30 at pages 12-13 (for Model D-101) and in Exhibit 32 (the centerfold pages, 12-13). In each of these schematic circuit portrayals, in the upper panel, labeled RF-CHASSIS, the portion on page 12 of Exhibit 30, and the left hand page of the centerfold page in Exhibit 32, there is a capacitor marked "C41", which appears very near the bottom of the upper panel of the two panel drawing below the assembly marked "Multivibrator". That capacitor is identified as a 5600 pf multivibrator feedback capacitor. It is directly related to the pulse frequency range of the Diapulse 101 and 102 modalities. See Exhibit 30 at page 24, part No. BP2352; Exhibit 32, page 23, part No. BP2352.

As noted above, the treatment head of the Diapulse device is in effect an induction coil and the inner diameter of the coil is in the order of five inches. Yet it is used both for local application, as for example ⁱⁿ treatment of otitis media, and for a wholly different kind of application: that is, application over the liver and adrenal glandular regions where it is claimed to function to stimulate body systems broadly, and by such stimulative reinforcement of natural curative processes of the body, to ameliorate conditions affecting remote parts of the body, including the toes.

While the government has seized a number of Diapulse units for condemnation from the possession of practitioners, where used, after shipment in interstate commerce, in

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allegedly therapeutic treatment of disease conditions, by far the greater number of the Diapulse machines sold and delivered in this country remain in the hands of the institutions and practitioners, including chiropractors and masseurs as well as medical doctors and physical therapists, who used them as therapeutic devices before the injunctions in the present case. Although there is no contention that defendants have failed to comply with the mailing and notice requirements of Paragraph V of the permanent injunction, the evidence indicates that the possessors of the devices still have in their possession the Diapulse literature with its elaborate teachings of the electromagnetic therapeutic treatment.

Before the entry of the final decree in the present case and as early substantially as the date of the rendition of the final decision in the present case, defendants evolved the concept of the P/EmF. That concept was to provide a relatively inexpensive means of converting the Diapulse machine to a machine to be called P/EmF which would have an "extended range" of application in the sense that it would have an additional range of pulse frequencies extending from about 600 pulses per second to approximately 2800 pulses per second and would have an increase in maximum peak power from 945 to 2153 watts. The converted device would, in all of its principal operating parts, including the treatment head, be the Diapulse device. It would continue to be a pulsed

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electromagnetic modality operating with short wave high frequency at 27.12 megahertz, using an input voltage of 117 volts at 60 cycles alternating current and 5-1/2 amperas. The duration of each pulse would as before be 65 millionths of a second at every pulse-frequency level. The difference would be the introduction of a higher power range, between 945 watts and 2153 watts and the higher pulse frequency range from a top frequency of 600 pulses per second to a top frequency of approximately 2800 pulses per second. The extended range of pulse frequency would, however, to some extent be offset by a compensating reduction in the available peak power, the highest peak power being available only at the lowest pulse frequency setting and the lowest peak power being available at the highest pulse setting only. The annexed Tables A and B show the contrasting peak power, average power, pulse frequency and "duty cycles" of the two devices.

The P/EmF conversion kit included a "relay" and a relay mounting socket and an example of these is contained in Exhibit 21: the "relay" is the device enclosed in the clear plastic enclosure, and the "mounting socket" with the tabs numbered at the base of each tab on the mounting socket is the white plastic body that mates with the prongs and screw at the base of the relay. Also included in the kit was a 750 PF capacitor, and this is identifiable in Exhibit 21 as the

small yellow pill-like disc with two wires extending from it which is marked "X5F, RMC, JL750, 10%". With each modification kit DCA Leasing Corporation sent to the consignee a letter enclosing a sheaf of papers typified by Exhibits 25 (addressed to Gilbert Cook), Exhibit 41 (addressed to Melvin C. Appel, Professional Electronics, Inc.), Exhibit 61 (shipped to Zimmerman and by his organization given to Gerald M. Rodgers at the time his Diapulse machine was exchanged for a P/EmF machine in July of 1972), and Exhibit 31, first pages (as obtained by FDA).¹ Among the pages included in the sheaf in each case is one page entitled "EXTENDED RANGE FOR RF CHASSIS MODIFICATION PROCEDURE" and Paragraphs numbered 4, 5 and 6 on this page of instructions cover the single critical change in the entire modification kit approach. With the aid of "RF Chassis Component Location" sheets 5 and 7 and other sheets, it will be seen that the capacitor C41 is cut out of its old location and is transferred to two terminals of the newly installed relay socket and relay, and that the new 750 PF Capacitor is installed, between two of the other terminals on the relay socket (the terminal lugs used are 2, 3, 6 and 7). The new relay makes it possible either to switch the 5600 PF capacitor into the circuit, retaining the capability to control the pulse repetition frequency from 80 to 600 pulses, or alternatively to switch the new 750 PF capacitor into the circuit, making available a range of pulse frequencies

from around 600 to approximately 2800 pulses per second. Both capacitors are stock items obtainable in commercial electronic supply sources. The rest of the materials in the kit have subsidiary and somewhat mechanical roles connected with the elimination of the watt meter that appeared at the left of the Diapulse panel and which was parasitic and not integral to the circuitry of the Diapulse machine, the installation of the switch at the far left of the panel for switching between the two pathways furnished by the relay between the 750 PF path and the 5600 PF path, and accompanying panel lights to show which path was in use, etc. While the peak power of the device was materially increased, [redacted] [redacted] from 975 watts to 2153 watts, that change did not require the introduction of any new major component, or the substitution of any new component for an old major component.

The evidence concerning the operating characteristics of the Diapulse as modified, when used in the range of 80 to 600 pulsations per second, is not altogether satisfactory; however, the preponderance of evidence is that use of the modification kits as sent out in June, July and the first part of August 1972, in accordance with the accompanying instructions, gave the modified Diapulse devices a design output, as P/EmF devices, when operating at 80 to 600 pulse frequency, identical with that of the Diapulse D-101 and D-102. At the higher range of around 600 to around 2800 pulsations

per second, (except in the case of the Appel device which was deliberately retuned to substitute an 80 millionths of a second pulse length) the peak average wattage at highest setting would be in approximately the range of 90 watts. The device tested at the Federal Communications Commission was a little higher in pulse frequencies at each setting. It had come from Gilbert Cook in Tampa and was modified from a Diapulse under the direction of Robert E. Byrum. The "P/EmF" as thus produced in accordance with the installation instructions sent out by DCA Leasing Corporation duplicated in every particular the capability of a Diapulse device of the D-101 and D-102 kinds. Any possessor of a P/EmF device produced through the use of the modification kit to modify a Diapulse D-101 or D-102 who had theretofore used a Diapulse device for experimentation, test, or as a therapeutic instrument, could use the P/EmF device exactly as he had used the Diapulse device without any change whatever in procedures. If he did not use the 7-12 range that made available pulse frequencies from 600 to 2800 pulses per second, there was no difference whatever in the utility and capability of the machine. Use of the P/EmF in the setting 7-12, 600 to 2800 pulses per second, range increased average wattage from the peak of about 38 watts in the lower, 6-12 range to a peak of 90 or 100 watts at the higher settings, 7-12, of the device. Nothing in any of the literature sent out with the modification kits for use in connection with the Diapulse device as modified distinguished any point at which a difference in operating characteristics

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from the older Diapulse machine took effect, and nothing in any of the literature made any specific recommendation about the settings at which treatment for the various conditions said to be treatable by the device should be treated. The only guide suggested was the patient's response to a sensation of increased temperature. To a convinced user of Diapulse, in consequence, the effect of the modification would simply be to enable him to resume treatment just as before with the unmodified Diapulse under the impression that he had, possibly, now in his possession a device which had not been disapproved by the FDA or by any Court.

The four page P/EmF brochure distributed with the modification kits is phrased exclusively in terms of heat treatment through use of high frequency diathermic currents locally applied to heat superficial and deep tissues. However, while noting that, "The beneficial effects of diathermy are derived solely on the basis of heat produced," the brochure makes it plain -- in a legend just under the table of physical conditions for which the apparatus may be used -- that the converted unit will produce only enough heat to raise the temperature of deep muscle tissue 2 inches below the surface of the mid-thigh from 98.6°F to 104°F in an average time of less than 15 minutes with the switch in "up" position and both the penetration and pulse frequency dialed to their highest settings of 12 and 6. That is, the users of the Diapulse device (and the modification kits were necessarily addressed exclusively to owners and users of existing

Diapulse machines) were at once warned that the heat effect, the diathermic effect, was characteristic only of the extended range introduced at pulse frequencies from 600 to 2800, and that the device delivered the characteristic Diapulse treatments as illustrated in Exhibits 50, 51 and 52, issued in 1968 and 1969, unless the new switch was flipped up, through use of the device at 80 to 600 pulses per second.

The Diapulse brochures of 1968 and 1969, Exhibits 50, 51 and 52, emphasize the idea that clinical and experimental studies showed that many of the effects of high frequency energy "are due to electromagnetic effects other than heat. DIAPULSE was developed to take advantage of this important finding, and to increase the range of application of this valuable new form of therapy." (See Exhibit 52.) The same brochure emphasized that the time lapse between electromagnetic impulses gave "ample time for dissipation of any heat which may be produced by the energy burst" permitting deep penetration of high intensity "with no significant rise in temperature, either locally or systemically." The brochure asserts that when applied over the epigastric area (roughly frontally at the approximate top of the abdomen, see Exhibit 50) "DIAPULSE therapy is capable of increasing peripheral blood flow without hyperpyrexia" (Exhibit 52). Similarly, Exhibit 51 of 1968 emphasized the Diapulse as emitting "pulsations of high intensity electromagnetic energy designed to accelerate normal healing without danger of hyperpyrexia or overheating of tissue," permitting "deep penetration without any significant increase in temperature either locally or systemically."

The brochure accompanying P/EmF suggested nine therapeutic uses of the modified device. Three of these had affirmatively been found by the jury in the Connecticut case to be false or misleading representations contributing to the finding of misbranding. The P/EmF brochure lists osteoarthritis as one condition for which "diathermy is useful" and osteoarthritis was a condition for which the jury found that a false claim was made for Diapulse. The P/EmF brochure lists "peripheral vascular disease" and states that for patients having an occlusive arterial disease it might be advisable to apply diathermy to the upper portion of the thighs, etc. The Connecticut jury had found the Diapulse falsely or misleadingly branded in claiming efficaciousness for treatment of occlusive vascular disease and peripheral vascular insufficiency. The P/EmF brochure lists otitis media as an infection for which patients could occasionally obtain relief by heat applications. The Connecticut jury had found the Diapulse device also misleading in its claim to relieve otitis media and ear conditions.

Reference to the charge in the Connecticut case, to the exceptions taken to the charge, and to the request for supplementary charge show that the jury's responses to the question whether false or misleading statements were made with respect to some 121 different conditions were given in the

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understanding that a general verdict of misbranding would be found if even one misleading or false statement was included in the broadly defined "labeling" of the seized Diapulse device. The Court did not require the jury to pass on all 121 listed ailments or conditions; the Court requested the jury to answer "yes" as to those ailments or conditions about which the jury was unanimous in finding that a false ~~or~~ misleading claim had been made. The Court explicitly refused to have the jury write the word "no" next to those conditions which in their unanimous opinion were not misrepresented, that is, conditions about which efficacy-claims were made ^{and} ~~the~~ claims ~~were~~ were neither false nor misleading. Hence, the jury's verdict affirmatively and unanimously finds that Diapulse had been falsely or misleadingly represented as therapeutically useful for each of the 49 particular ailments or conditions as to which it answered, "yes". It made no finding that the device had any therapeutic utility as to any of the ailments or conditions left blank.

The jury was authorized to find that a claim was false or misleading if it found (a) that a particular claim of therapeutic utility was the subject of a difference of opinion among experts qualified to have an opinion by their scientific training and experience and (b) that the label failed to disclose the existence of that difference in ² opinions. As the Court put it (Tr. 2726-2727)

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"Now, the failure to disclose the existence of an honest difference of opinion, as I say, might make the opinion expressed in the labelling misleading because you havent told about the other difference of opinion; but this other difference of opinion, in order to affect the label, should be a material weight of opinion contrary to what the label says. . . . if you should find that there were any significant studies unfavorable to Diapulse and if you should find that the Diapulse Corporation knew of these studies or should have known of them and didn't publish them or distribute them as part of the labelling, then on that ground alone, the labelling was misleading because only half a story is told."

The brochure accompanying P/EmF contained at its third page following the listing of the "Operating Procedures" a note to procedure No. 3, and its reference to settings 1 through 6 of the pulse frequency dial. That note read:

"Note: The F.D.A. and many medical authorities are of the opinion that these lower settings are medically useless."

While there is definite and credible evidence that dealers were instructed in connection with the distribution of P/EmF to take up old Diapulse literature from users of Diapulse machines when the P/EmF modification kits were used to convert their machines or their machines were exchanged for converted machines, there is evidence that one dealer at least failed to do this in at least one case, and there is little evidence that the instructions were practical or were or could be carried out systematically. It is moreover manifest that since the Diapulse machine had been distributed in large numbers for a number of years before the adverse finding in the

Connecticut case and a flow of literature to Diapulse users was kept up at least into 1969, the mildly unobtrusive foot-note about FDA and medical authority opinion, and the statements about the therapeutic use of heat-diathermy can hardly be supposed adequate to efface the effect of defendants' systematic indoctrination of Diapulse "therapists" with the athermal electromagnetic therapy concept, particularly in view of the practitioners' stake in continuing the use of his therapeutic method and modality without change.

Moreover the facts do not warrant putting the P/EmF forward as a diathermic heat-treatment device.

The evidence is that before the introduction of Diapulse there were no pulsed diathermic machines used therapeutically for diathermic heat therapy. After the introduction of Diapulse one or several pulsed diathermic heat-treatment devices did appear, but they remained exceptional and not in the main stream of conventional diathermic heat treatment devices. In very general terms, diathermic heat therapy devices operate in the range of 100-400 average watts and, in general, aim at increasing tissue temperatures at depth to the range of 104° to 113.9°F. The Federal Communications Commission has issued something like 300 type-approvals for diathermic devices with power capabilities in the range from 5-7 watts to 600 watts.

Specialists in Physical Medicine and Rehabilitation recognize two basic types of heating devices used in heat

therapy: that is, superficial heating devices such as hot pads, electric heating pads, heat lamps, hot water or paraffin applications; and deep heating devices, including such devices as short-wave diathermy devices, microwave diathermy devices, and ultra-sound devices. The term "diathermic devices" means devices used as a means of heating tissue deep in the body where heat is the indicated therapy. Short-wave and microwave diathermy alike are radio transmitted and produce heat in body tissue by induction: they induce a flow of current in the body and tissue resistance to the flow of the current evolves heat. Ultra-sound utilizes sound wave, and the resistance (or impedance) to the propagation of the sound wave in the tissue converts the sound energy into tissue heat.

The evidence at the trial before Judge Rosling was that diathermy was recognized as having specific physiological capabilities including: relief of spasm; relief of pain apparently by means of induction of nerve action; facilitating the restoration of resiliency to long immobilized tissue (as in fracture cases); increasing the blood flow; increasing capillary permeability; increasing the migration of antibodies across capillary tissues; increasing the migration of white cells to capillary tissues in areas of infection; the removal of the by-products of inflammation; change in the visco-elastic property of tissues; and, broadly, inducing a euphoric sense in the patient. The evidence was that the consensus of the medical profession was that the sole therapeutic effect of diathermy devices was in their heat producing capacity, and

that the electromagnetic penetration considered independently as electromagnetic penetration was wholly without therapeutic value. The evidence was that the heat producing capability of radio frequency diathermy was a function of the average wattage delivered by the device to the human tissue. It was also the evidence that there was no way of determining externally and objectively the appropriate dosage for different physiological conditions and treatments, and that the therapist had to be guided by the heat response of the patient. The evidence was that patients have different tolerances for heat.

(Dr. Silverman apparently supposed that all diathermy devices were pulsing devices and in this respect, as the Court sought to point out to him, was quite wrong; a reference to Exhibit 69, which he drew, shows that he was confusing the input current from the household socket, which operates at the very low frequency of 60 cycles per second, and was thinking of alternating current as a pulsating rather than a continuous current. It is not. It is continuous alternating current. He thought, too, that half-wave rectification of 60 cycle domestic current was "pulsed" current. It is not so considered but is very familiar ^{as} rectified current. Neither 60 cycle unrectified current nor the 60 cycle rectified current is pulsed high frequency as used in describing the pulsed Diapulse machine, and the one or two other pulsed diathermic devices said to function at true diathermic heat therapy wattages. See Transcript June 16, 1972, pages 51A-71A).

The elevation of the temperature of human tissue at depth through short-wave electromagnetic means takes place over time as the energy is applied and reaches a temperature plateau marking the balance between the evolution of heat in the tissue and the dissipation of the induced heat through the circulation of body fluids through the heat-elevated tissues, the heat itself stimulating an increase in such circulation; a cessation of application of the heat producing energy could significantly cool the tissue only over minutes of time. Hence, with such a device as the Diapulse, even operating at only 80 pulsations a second, the current flows for one 65 millionths of a second during each of 80 pulses a second. Each pulse measured from the moment the one 65 millionths of a second impulse starts to the moment when the next 65 millionths of a second long pulse starts at 80 pulsations per second would be what is called 12.5 milliseconds, that is, 12-1/2 thousandths of a second. No significant cooling after a significant elevation in tissue temperature could occur within 12-1/2 thousandths of a second. If the pulsations per second increase to 600 or to 2800 pulsations per second, the ratio of time "on" to time "off" rising, and the length of each individual "off" time varying inversely with pulse frequency, the cooling time would be ever more sharply abridged as frequency rose, and the possibility of significant cooling would be ever more radically excluded. From this it follows that from the viewpoint of the heat treatment

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tissue at depth, the "pulsation" of short-wave high frequency electromagnetic energy is significant only as a control of average watts of energy delivered to the tissue over the whole period of treatment. The pulsation qua pulsation is therapeutically meaningless and does not function as a means of tissue cooling between intervals of tissue heating.

There is evidence that the use of a conventional diathermy device and the Diapulse device where each was producing the same average wattage produced no difference in effect on the subjects treated and that in consequence it was correct to conclude that the radically higher peak power interruptededly in the Diapulse device produced no difference in its effect on the tissues from the effects produced at the same average wattage by conventional diathermy devices. There was evidence that further work along the same line showed no difference in the thermal or in the physiological effects of the conventional diathermy device and the Diapulse device on tissue both operated at the same average wattage.

The evidence of Dr. Silverman was that the optimum amount of energy for therapeutic diathermy would be between 50 and 100 watts and he was of the view that some diathermy equipment of the conventional sort was capable of delivering 200 watts of average power. Dr. Silverman's range of 100 watts referred, he explained, to the amount of electro-magnetic emanation from the treatment head, and on the same basis the Diapulse delivered 15 watts at the treatment head.

when he and his team used the Diapulse device they found no physiological effect that was traceable to the device, even though it was equally powerful to produce the same electromagnetic effect. One produced also what was the so-called

The evidence is that the Diapulse device is, at the point of application, a minor fraction of the power of thermic machines and has therapeutic heat capability nil. It was capable because of the unavailability of the device in human tissue, but was not verified as flowing in consequence of its heat elevation effect. The pulsed peak power was measured in glass from a thermocouple. To the extent that

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technical assistant "beefed up" the standard
that they used. Dr. Silverman was satisfied
ical effect produced by the Diapulse device
anything other than its heat producing ef-
the heat produced was, at most, mild heat,
roduced by ordinary diathermy device used
the heat effect. The only identifiably
fect produced by the Diapulse machine was
by conventional diathermic devices, and
lled pearl chain effect.

ence then fairly conducts to the conclusion
device produced at the treatment head, that
f application to the patient, only a very
the wattage produced by conventional dia-
nd that the diathermic, that is, the thera-
py of the Diapulse device was substantially
e of modest elevation of tissue temperature
oidable effect of inducing electric current
t such physiological phenomena as could be
from the use of the Diapulse device were
s heat elevating effect, inadequate as that
ct was for general therapeutic purposes.
er characteristics of the Diapulse were mean-
apeutic and medical modality point of view.
the Diapulse inevitably raised tissue

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temperature the "off" periods between the pulses of energy were insufficient in duration for any significant cooling effect to take place. Hence, neither the high peak power nor the pulsed nature of the Diapulse kind of electromagnetic energy had any therapeutic or medical significance. The electronic or electromagnetic capabilities of the Diapulse as a medical modality were bounded by and limited to the instrument's capacity to deliver an average wattage at the treatment head, at the point of its application to the human body. Neither pulsation nor peak wattage had any therapeutic utility or capability not evinced by conventional diathermic machines capable of producing the same average wattage at the point of application to the human body.

Exhibit W, descriptive of one form of P/EmF, with a rewritten brochure, has not precisely the same characteristics as Diapulses modified by the P/EmF conversion kit. Among other things it includes directions for the replacement of a 15,000 Ohm 2 watt resistor, R61, with a 33,000 Ohm 2 watt resistor to be connected from the potentiometer or variable resistor marked R60 to the chassis, with consequent increase of average wattage capacity from something in the order of 137 average watts to something in the order of 165 average watts. In addition, the lower range of pulse frequencies, 30-600, has been modified so that the lowest setting would deliver 8.6 average watts and the highest setting in the lower range would deliver 56 watts rather than the 35-38 watts characteristic of

the Diapulse machine which was also, and evidently, the design capacity of the lower range of the P/EMF kits sent out in June, July and August of 1972. The device of Exhibit W, tested, however inadequately, for its capacity to raise the temperature of human deep muscle, had the capability when set at its very highest settings (6 and 12) in six of eight cases of elevating the deep muscle temperature to points between 40°C and 41.1°C; it thus could at its topmost pitch of effort just reach the minimum deep tissue heating requirement for classification as an acceptable diathermic apparatus under the American Medical Association standard (Exhibit Y). The test data in Exhibit W, Tab.VII, report that the initial temperatures of the deep muscle at the start of each test, except one, was above the core body temperature of 37°C which is normal for humans; the room temperature was 30°. There is no suggestion that the apparatus could function in the deep tissue range of 104° to 113°F. generally accepted as being the therapeutic range of standard diathermic treatment. Of the diathermic devices listed in the AMA manual, those which give their output in watts (and most of them do not) show outputs of 170-225 watts, 350 watts, 445 watts (with air-spaced plates) and 395 watts with hinged drum; all of these data are from the very early 1950's.

It was concluded when the government rested its case that it would be legal error to submit the case to the jury,

connection with the Diapulse devi s as modified distinguished
any point at which a difference in operating characteristics

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since the jury could not, on the evidence, find beyond a reasonable doubt that the shipment of the P/EmF to Las Vegas in June violated the temporary restraining order since its prohibition applied only, it fairly appeared, to Diapulse devices substantially identical with the one under seizure in Connecticut. Similarly, the charges of Paragraphs 6, 7, 8, 9 and 10, dealing with the shipment of P/EmF modification kits, it was concluded, could not without error be given to the jury to decide since on the evidence it was not considered that the jury could find beyond a reasonable doubt that the P/EmF kits were "articles of device known as DIAPULSE, or any similar articles of device . . . in whole or in part, assembled or unassembled," within the required plain meaning of the permanent injunction. The charge of Paragraph 11 was not supported by evidence from which it would have been possible for the jury to find beyond a reasonable doubt that the mailing involved was an act done with respect to an article held for sale which resulted in its being misbranded.

While the shipments of the kits were not of themselves shown to constitute criminal contempts that could be given to the jury on all of the evidence it must be concluded that shipments of the P/EmF kits, and the use of equipment converted through use of the kits, constituted evasion and not avoidance of the strictures of the permanent injunction and its purpose. The same conclusion must be reached as to kits made up in conformity to Exhibit W. Both the kits shipped in

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to their highest settings of 12 and 6. That is, the users of the Diapulse device (and the modification kits were necessarily addressed exclusively to owners and users of existing

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June, July and August of 1972 and any kits made up in accordance with Exhibit W, would in no sense be conventional diathermic modalities of the kind used and useful in diathermic heat therapy. On the contrary, kits of either type would enable practitioners already learned in the use of Diapulse to continue the use of the devices as Diapulse modalities in accordance with the teachings of defendant over the years. The addition of an extended range making possible the use of pulse frequencies as high as 2800 pulsations per second and 137 watts of average power (with peak power at 753 watts at that point) does not alter the case. It may be that by using the device to deliver its greatest average wattage at the settings of 12 and 6, the device could, in a room where the temperature is 80°, barely reach in six-eighths of the instances of its application the lower edge of the range of tissue temperatures at depth at which diathermic heat therapy is administered, but that hardly constitutes the articles standard diathermic heat-therapeutic devices. They would remain characteristically devices essentially designed and suited to implement Diapulse therapy, that is, the use of electromagnetic induction with minimal increase in tissue temperature as electromagnetic therapy accompanied by some unavoidable but unsought-for increase in tissue temperature.

The present set of proceedings was commenced at the end of 1965. In the 8 years that have elapsed since that seizure, it is apparent from the testimony in the present case

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that the defendants have not retreated from their obdurate insistence on pursuing their own scheme of therapy, and that defendant and its responsible officers have not at any time sought genuinely to depart from adherence to their conviction but, rather, have sought repeatedly to induce the Food and Drug Administration to authorize activities which paid lip-service to heat therapy through the use of electromagnetic energy while in reality making it possible to put back into service the thousands of Diapulse devices already in existence and to ship more such devices with such minimal additions to the by-product heat producing capability of the Diapulse device as would enable it to pass muster in mild temperature diathermic heat therapy while remaining essentially an electromagnetic device which, it could always be argued, produced its physiological effects, if any, through electromagnetic therapy and not through heat therapy. The modality would have remained at all times a pulsed device characterized by having its current "on" a minor part of the time (in Exhibit W, 18.2% of the time at the highest pulse frequency and one-half of 1% of the time at the lowest pulse frequency). The device would have very high peak power (ranging up to 2153 watts at the lowest pulse and highest "penetration" settings). The practitioner would possess this modified instrument and his one-sided indoctrination over years of practice with Diapulse in electromagnetic therapy, based ^{on his} ~~on his~~ knowledge of the extensive literature sent him by defendants; the instrument in his possession would have as its major and ineffaceable design

characteristic~~s~~ capabilities that had no explanation except their selective suitability to the practice of electromagnetic therapy as such and as contrasted with diathermic heat therapy.

At the same time it must be recognized that the ~~that~~ economic waste will inevitably be implicit in the systematic surrender for destruction of all existing Diapulse devices (except those that can be used under proper controls for experimental purposes by responsible investigators) is desirably avoided if that is possible without compromise of the principle of the Connecticut decision and of the decision in this Court of Judge Rosling. In addition, the defendants are entitled to a clear command and the government to a rigorous order so that there cannot be any evasion and extirpation is effective.

It would appear that Paragraph II of the permanent injunction should be elaborated and refined so that Section III of the decree will have its intended effect. The proposal of the government to add a new set of paragraphs, rather than to modify the existing paragraphs would present a decree of great length and since it would be desirable to have the entire decree in a single document for rapidity and ease of dissemination and understanding, it would be desirable to avoid repetition. Section VIII as suggested by The Government's suggested Section VIII par. B and par. C appear superficially to be identical with Section III par. A sub pars. 1 and 2 of the present permanent injunction, and that can be avoided.

Proposed Section VIII par. A introduces the critically new matter. Suggested par. A, while apt to describe P/EmF, may well have the disadvantage of specificity in the present context.

Section II might be rephrased thus:

"The DIAPULSE devices referred to in this injunction include in addition to the DIAPULSE devices heretofore sold in this country and abroad as Models D-100, D-100J, D-101, D-102, and D-103; ~~the~~ the said devices or any of them as modified to convert them into P/EmF devices (as described in Exhibits etc.), and the components or kits or parts of any assemblies or sub-assemblies thereof used to effect such conversions; any short-wave, high frequency, electromagnetic modality made or adaptable to radiate pulsed short-wave high frequency, electromagnetic energy unless (a) the peak power available at any setting of the device does not exceed twice the average wattage at such setting, and (b) it is capable of raising the temperature of deep human tissue at a depth of 2 inches in the thigh muscle of living human subjects from a core body temperature of 98.6° to 104°F in 20 minutes or less, at a majority of its operational settings, and (c) it is capable of raising such tissue at such depth to a range of temperatures from 104° to 113°F at a series of readily selected settings of the device."

The language of Section III, par. A should be modified, probably in the part preceding sub pars. 1, 2 and 3 to

cover conversion assemblies, subassemblies, kits, components, or instructions, manuals or pamphlets. In Section IV, the reference to 21 C.F.R. 1.106 ought probably to be clarified and expanded to make clear that it covers any device in amended Section II, and consideration should be given to the matter of requiring defendants to clear any medical modality that they desire to sponsor or disseminate in this country. It should be understood that the advance clearance requirement is not normally required for devices but is exceptionally required in this case and consciously borrows from new drug procedures.

A new section or sections, functioning as did Section V, should ~~be~~ ^{be} in the amended decree and, perhaps, Section V can be retired as fully performed and devoid of prospective effect. Proposed modifying paragraphs should be settled on notice and either party is free to propose appropriate language within the limits indicated by the sense of this decision. Ten days notice of settlement is to be given to the other side so that there will be ample time to exchange ideas before the amendatory language is adopted. The adoption of the amendatory language which can appropriately take the form of an amendatory decree should be followed by a resettlement of the entire decree so as physically to incorporate the new material.

Paragraphs IX and X, as proposed by the Government, present points of principle as to which the defendants should probably be heard on the settlement of the further decree.

Specialists in Physical Medicine and Rehabilitation

recognize two basic types of heating devices used in heat

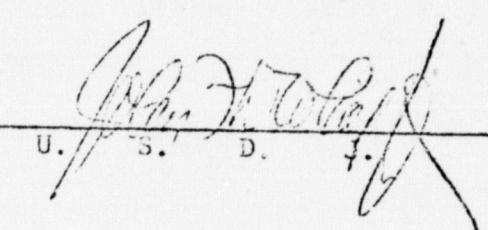
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It is so ORDERED.

Dated: Brooklyn, New York
May 7, 1974.



U. P. S. D. J. P. D.

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the medical profession was that the sole therapeutic effect of diathermy devices was in their heat producing capacity, and

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FOOTNOTES

1. Exhibit 67 seems to be the set of instructions sent to Groves in Missouri from New Hyde Park.
2. See 21 C.F.R. § 1.3 for the propriety of the Court's language.

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Table A - Diapulse
D101 - D102

Pulse Frequency per second	Dial at	Peak and Average Power in Watts						* "Duty Cycle"
		1	2	3	4	5	6	
80	1	293	390	483	585	780	975	1/2 of 1
		1.52	2.03	2.53	3.04	4.05	5.07	
160	2	293	390	483	585	780	975	1.
		3.04	4.05	5.07	6.08	8.1	10.1	
300	3	293	390	488	585	780	975	1.9
		5.7	7.6	9.5	11.4	15.2	19	
400	4	293	390	488	585	780	975	2.6
		7.6	10.14	12.68	15.2	20.3	25.3	
500	5	293	390	488	585	780	975	3.25
		9.5	12.65	15.25	19	25.3	31.6	
600	6	293	390	488	585	780	975	3.9
		11.4	15.2	19	22.8	30.4	38	

*That is, the percentage of each second during which the "current" is "flowing" at the pulse frequency shown at the left.

Each "pulse" is 65 millionths of a second in duration.

Peak power is given in upper line, average power in lower line at each pulse frequency setting.

The device operates at 27.12 megahertz frequency.

The power source required is 117 volt 60 cycle AC current at 5.5 amperes.

Table B - P/E in F
 RS 2800
(Exhibit W)

Pulse Frequency per second	Dial at	Peak and Average Power in Watts						* "Duty Cycle"
		1	2	3	4	5	6	
80	1	1553 8.6	1730 9	1776 9.03	1788 9.3	1846 9.6	2153 11.0	1/2 or 1%
160	2	1451 15.1	1480 15.4	1548 16.1	1586 16.5	1615 16.8	1817 18.0	1.04%
300	3	1358 26.5	1379 26.9	1384 27.0	1400 27.3	1400 27.3	1512 30.9	1.95%
400	4	1357 35.3	1349 35.8	1392 36.2	1415 36.8	1423 37.0	1588 41.3	2.6%
500	5	1276 41.5	1307 42.5	1326 43.1	1341 43.6	1378 44.8	1516 49.3	3.25%
600	6	1261 49.2	1264 49.3	1282 50.0	1333 52.0	1358 53.0	1487 56.0	3.9%
600-700 ⁺	7	1325 51.7	1341 52.3	1356 52.9	1420 55.4	1420 55.4	1461 56.0	3.9% + 10%
1000	8	1186 77.1	1209 78.6	1232 80.1	1255 81.6	1278 83.1	1307 85.0	6.5%
1600	9	985 102.5	1000 104.1	1018 105.9	1034 107.6	1050 109.3	1051 109.3	10.4%
2100	10	827 112.9	852 116.4	866 118.3	879 120.1	893 ⁺ 121.9	893 123.8	13.65%
2500	11	728 118.3	750 121.9	761 123.8	772 125.6	796 129.4	800 131.0	16.25%
2800	12	659 120.1	669 121.9	700 127.5	710 131.0	732 135.0	753 137.2	18.20%

*That is, the percentage of each second during which the "current" is flowing" at the pulse frequency shown at the left.

Each "pulse" is 65 millionths of a second in duration.

Peak power is given in upper line, average power in lower line at each pulse frequency setting.

The device operates at 27.12 megahertz frequency.

The power source required is 117 volt 60 cycle AC current at 5.5 amperes.

DEFENDANT'S MEMORANDUM ON SETTLEMENT
OF A RESETLED PERMANENT INJUNCTION

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

-against-
Civil No. 68-C-391

DIAPULSE CORPORATION OF AMERICA,
also known as THE DIAPULSE MANU-
FACTURING CORPORATION OF AMERICA,
a corporation,

Defendant.

DEFENDANT'S MEMORANDUM ON SETTLEMENT
OF A RESETLED PERMANENT INJUNCTION

I

The Plaintiff's Submission

The 12-page "Permanent Injunction" proposed by the plaintiff appears to have been drawn with the view of thereby putting the defendant out of business - despite this Court's statement in its Memorandum and Order of January 29, 1974 (at p.9):

"Nothing on earth, of course, could prevent defendants from making and marketing a conventional diathermy machine ..."

and despite this Court's statement in its Memorandum of May 7, 1974 (at p.33):

DEFENDANT'S MEMORANDUM

"... it must be recognized that the economic waste that will inevitably be implicit in the systematic surrender for destruction of all existing Diapulse devices (except those that can be used under proper controls for experimental purposes by responsible investigators) is desirably avoided if that is possible without compromise of the principle of the Connecticut decision and of the decision in this Court of Judge Rosling. ..."

Indeed, plaintiff goes further and seeks to have this Court add an interdictment of shipment abroad. It seeks to achieve that by having, in its proposed Section II(A), the "term 'interstate commerce'" defined, for "the purposes of this Injunction", as "commerce between any State or Territory or any place outside thereof ... Provided, that the provision of 21 U.S.C. 331 shall not be construed to exempt any Article of Device Diapulse from any of the restraints of this Injunction". That is proposed despite the express exclusion, in and by Section 331, from the Food and Drug Act of devices "intended for export" if such device "(1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export"; and even though the "jurisdiction" of this Court,

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average watts and the highest setting in the lower range would deliver 56 watts rather than the 35-38 watts characteristic of

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under 21 U.S.C. 332, is limited to "restrain violations of Section 331 ..." of Title 21.

Plaintiff's submission also aims to defeat this Court's dual concern - indicated in the passage quoted above from page 33 of the memorandum of May 7, 1974 - that there should be due opportunity for present possessors of Diapulses to have them converted to diathermy modalities and that unconverted Diapulses should be available "for experimental purposes by responsible investigators". Plaintiff seeks to accomplish such defeat by circumscribing each of those authorizations with such onerous restrictions, including FDA advance approval, as to render the authorizations inoperative.

In addition, the plaintiff proposes the imposition upon the defendant of continuous FDA "free access" to every of its "offices, plants, factories, warehouses, storage facilities, or other establishments" and full opportunity during all working hours to inspect and copy and photograph "all pertinent equipment, finished and unfinished materials, containers, and labeling ... records, files, papers, processes and facilities bearing on whether any articles of device have been or are being manufactured, processed, packed, transported, or

DEFENDANT'S MEMORANDUM

held in such place". What provisions in the Food and Drug Act envision, contemplate and authorize such a perpetual continuous ^bsurveillance, seige, occupation and search of defendant's private premises and its private property?

II

Defendant's Submission

Defendant, on the other hand, submits a simple, brief (yet comprehensive) and clearly understandable proposed resettled permanent injunction which, it is submitted, carries out in full the "sense of [this Court's] decision" of May 7, 1974. In explanation of the reasons for what defendant's submission contains and what it omits, the following is offered.

By proscribing introduction or delivery into interstate commerce of

"any short-wave, high frequency, electro-magnetic modality or device - in whole or in part, assembled or unassembled - for use on human beings, made or adaptable to radiate pulsed short-wave, high frequency, electro-magnetic energy"

unless it has the capabilities therein described and unless it is accompanied by the labeling therein stipulated, further definition is rendered unnecessary.

Thereby Diapulse is unmistakably, completely and

DEFENDANT'S MEMORANDUM

unconditionally barred from interstate commerce as is every other device that does not have the capabilities and labeling of conventional diathermy.

The specification suggested by the Court on page 34 of its memorandum of May 7, 1974 that "peak power available at any setting of the device does not exceed twice the available wattage at such setting" is omitted for the following reasons: (i) It is not possible to effect such a change in the existing Dia-pulses; thus inclusion of that specification would preclude conversion of those devices. (ii) That limitation is unnecessary since "average wattage" is the governing factor and the required average wattage is assured by the proposed requirements (a) and (b). (iii) If the reason for the limitation be an apprehension that therapists may prefer a modality with a high rate of pulsation in the belief that even though there is no accepted scientific evidence that the pulsation has any therapeutic effect, nothing is lost from the pulsation and something may be gained, we ask: what objection can there be to action on that basis if the therapist chooses to so act, what harm comes therefrom? (iv) Moreover,

DEFENDANT'S MEMORANDUM

we urge that the defendant should not be prohibited from marketing a highly pulsed diathermy modality when competitors are not impeded from so doing? For example, the Magnatherm range is from 700 to 7,000 pulsations per second and the range of Elmed's Ultramat Dual pulsation is from to , and Mark VII Thermatic from 80 to 2,600. Has the FDA taken any action against either of those? Does it intend to? If not, why should defendant be discriminated against?

Provision for advance clearance or approval by FDA is omitted because the provision of an absolute bar of interstate shipment of modalities that do not fully comply with the proposed very explicit specifications leaves nothing for FDA to pass on. Any interstate shipment by the defendant that does not fully comply with every specification would constitute a contempt of court, in addition to being subject to seizure and the other sanctions provided for by statute. Hence, the public needs no further protection. On the other hand, the requirement of advance clearance and approval by the FDA is likely to result in a frustration of the Court's intent to provide even-handed justice; this seems a fair

DEFENDANT'S MEMORANDUM

deduction from the nature and content of plaintiff's submission and the animus reflected thereby.

In support of the foregoing, we emphasize that the scope of the proposed Resettled Permanent Injunction submitted by the defendant is radically different from that of the present July 1972 judgment. That judgment dealt with and related to athermal Diapulse as distinguished from thermal diathermy; whereas defendant's submission totally bars Diapulse and authorizes only diathermy with its conventional labeling. Diapulse, in the adjudged circumstances, required special labeling justified by scientific research yet to be conducted. For that reason submission to and approval by FEA was required by the Court. None of that applies to the modalities to which the proposed Resettled Judgment would limit the defendant, the labeling of which is commonplace and the essentials of which are set forth in Section II(c) of the proposed resettled judgment. Limitation of the defendant to the commonplace and customary eliminates any need for placing defendant under restraints and requirements which Congress intentionally and deliberately refused

DEFENDANT'S MEMORANDUM

to authorize for devices.

In respect to proposed Section III, defendant submits that the suggested provisions are necessary to make clear both to the FDA and the defendant what is prohibited and what is not prohibited, especially since the FDA in its submission seeks explicit provisions to the contrary of what the law provides.

The defendant's submission reflects defendant's abandonment of all hope of ever convincing FDA that high pulsation has therapeutic efficacy. That, of course, is no reason for hamstringing further legitimate research. FDA's obdurate close-mindedness on the subject and its far flung efforts, here and abroad, to discourage and disparage such research, defendant submits, should not be assisted by judicial decree. If anything, FDA should be judicially admonished against such conduct. As far as the defendant is concerned, if and when scientific medical research and experimentation decisively vindicates defendant's faith, defendant expects to look to the Court for appropriate relief from the injunction. Until then, defendant is genuinely resigned to abstain completely and absolutely from interstate marketing of any athermal short-wave

DEFENDANT'S MEMORANDUM

therapy device or with athermal claims. It is in that spirit and to that end that defendant submits the accompanying proposed "Resettled Permanent Injunction".

Respectfully submitted,

Paul M. Nantz
COPAL NANTZ
Attorney for Defendant.

June 21, 1974.

present points of principle as to which the defendants should probably be heard on the settlement of the further decree.

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GOVERNMENT'S MEMORANDUM IN SUPPORT OF
ITS PROPOSED PERMANENT INJUNCTION AND
IN OPPOSITION TO DEFENDANT'S PROPOSAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X

UNITED STATES OF AMERICA,	:	Civil No. 68-C-391
Plaintiff,	:	
v.	:	MEMORANDUM IN SUPPORT OF GOVERNMENT'S PROPOSED PERMANENT INJUNCTION AND IN OPPOSITION TO DEFENDANT'S COUNTER-PROPOSED PERMANENT <u>INJUNCTION</u>
DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANU- FACTURING CORPORATION OF AMERICA, a corporation,	:	
Defendant.	X	

I

STATEMENT

This is a civil action for injunction under the provisions of the Federal Food, Drug, and Cosmetic Act. The defendant is the Diapulse Corporation of America, a Delaware corporation, having its principle place of business at New Hyde Park, New York. On July 18, 1972, an order of permanent injunction was entered prohibiting the defendant from, among other things, causing the Diapulse device or any similar device to be introduced or delivered for introduction into interstate commerce in violation of 21 U.S.C. 331(a) by reason of being misbranded within the meaning of 21 U.S.C. 352(a) or 21 U.S.C. 352(f)(1). The permanent injunction was affirmed on appeal on October 24, 1973, without opinion, United States v. Diapulse Corporation of America, 485 F.2d 677 (C.A. 2, 1973), and certiorari was denied on April 15, 1974, Diapulse Corporation of America v. United States of America, ____ U.S. ____ (No. 73-1117, 42 LW 3584, April 15, 1974).

This action grows out of criminal contempt proceedings alleging violations of the permanent injunction entered by this Court on July 18, 1972, and violation of a preliminary injunction entered by

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this Court and in effect from its affirmance by the Court of Appeals for this Circuit on March 20, 1972 [United States v. Diapulse Corporation of America, 457 F.2d 25 (C.A. 2, 1972)] until the entry of the permanent injunction. On April 12, 1974 the Petition for an Order to Show Cause for Criminal Contempt was dismissed on the grounds of the failure of the proof to make out a case to go to the jury. Tr. 644. Subsequent to that ruling the hearing of evidence continued on cross-motions by the parties for modification of the permanent injunction pursuant to paragraph VI of the permanent injunction.

On May 7, 1974, the Court entered its Memorandum incorporating Findings of Fact and Order. As provided by the Court, both parties have proposed language for a revised injunction. This Memorandum is in support of the Government's proposed injunction and in opposition to the defendant's proposed injunction.

II

ARGUMENT

A. The May 7 Order Of This Court Requires A Revised And Expanded Permanent Injunction.

The May 7 Memorandum and Order of this Court clearly requires a revised and expanded permanent injunction. Thus, the Court declares that "the defendants are entitled to a clear command and the Government to a rigorous order so that there cannot be any evasion and extirpation is effective". May 7 Opinion, p. 33. Further, the Court provides specific direction at p. 34 of its opinion with respect to the definition of the device which should be covered by the revised injunction; at p. 34-35 with respect to the coverage of assemblies, subassemblies, kits, and components; and at p. 35 with respect to clarification of the provisions requiring prior approval by the United States Food and Drug Administration of devices which the defendant may

GOVERNMENT'S MEMORANDUM

desire to sponsor and disseminate in this country.

Contrary to the defendant's proposed injunction, there is no indication in the Court's opinion that any prohibition currently in effect should be eliminated. While the defendant complains that the Government's proposed injunction is too broad and accuses the Government of having drawn the injunction with the view of putting the defendant out of business, these specific arguments have been previously decided by the Court of Appeals for this Circuit. In United States v. Diapulse Corporation of America, 457 F.2d 25 (C.A. 2, 1972) at p. 29, the Court of Appeals declared that:

[t]he injunction may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur. ... Nor can appellant complain that the injunction is impermissible because it will put him out of business. He "can have no vested interest in a business activity found to be illegal. It has long been settled that the [Food and Drug] Act itself is a constitutional exercise of the Commerce power. ..."

Thus, the government's proposed injunction is based not only on the injunction currently in effect but also on the directions provided by the Court in its May 7 Memorandum incorporating Findings of Fact and Order.

B. Proposed Section II.

This section of the government's proposed injunction provides definition of a number of terms used in the injunction. Since the proposed injunction would issue under the Federal Food, Drug, and Cosmetic Act, the definitions are those provided by the Act. The inclusion of definitions in the text of the injunction assures that there is no misunderstanding as to the precise meaning of the defined terms.

As the defendant recognizes [Memorandum, p. 2], proposed section II(A) includes a proviso that the export provisions of the Act,

GOVERNMENT'S MEMORANDUM

21 U.S.C. 381, shall not be construed to exempt any article of device Diapulse from any of the restraints of the injunction. This is intended to enjoin the exportation of Diapulse devices except upon compliance by the defendant with the provisions of the injunction which would condition the shipment of such devices on prior FDA approval. As the Court found, the defendant has shipped to foreign countries since the date of entry of the final injunction, Diapulse devices of the kind sold in the United States before the litigation in Connecticut and New York, and approximately 700 Diapulse devices have been made in this country and sold abroad. May 7 opinion, p. 3. The Court has noted that the defendant is entitled to a clear command and has specifically directed that the revised injunction should include Diapulse devices heretofore sold in this country and abroad. May 7 opinion, p. 34. Thus, the Government's proposed provision clearly advises the defendant that shipments of devices abroad are included in the prohibition of the proposed injunction.

C. Proposed Section III.

This section of the Government's proposed injunction defines articles of device Diapulse. The section follows the specific direction of the Court provided at p. 34 of the May 7 opinion. Thus, paragraph (A) defines the Diapulse device, (B) defines the P/EmF device, and (C) defines the modification kit. Paragraph (D) incorporates the Court's definition of covered devices as provided at p. 34 of the May 7 opinion with respect to peak power not exceeding twice the average wattage of any setting and the capability of any device to produce certain specified levels of tissue temperature elevation.

While the defendant contends [Memorandum, p. 5] that the conversion of the Diapulse device to meet the Court's requirements with respect to peak power is not possible, this consideration, if true, is irrelevant to the inclusion of this provision in the Government's

proposed permanent injunction. The reason for the limitation is clearly pointed out by the Court at p. 26 of its May 7 opinion where the Court points out that "pulsation qua pulsation is therapeutically meaningless and does not function as a means of tissue cooling between intervals of tissue heating". Nevertheless, the conversion of existing Diapulse devices, if accomplished according to the Government's proposed injunction, would require FDA approval. Thus, the defendant would have the opportunity to establish that an otherwise satisfactory conversion could not be accomplished under the proposed peak power limitation and to propose an appropriate alternative for approval by the Agency. Accordingly, the defendant's objection to the Court's peak power limitation is without merit.

D. Proposed Section IV.

This section prohibits the shipment of articles of device Diapulse accompanied by labeling representing that they are effective in the treatment of disease, accompanied by labeling which contains modification instructions, or which fail to bear adequate directions for use. This section also prohibits the doing of any act which would cause devices held for sale after shipment in interstate commerce to be misbranded in any of the ways specified in preceding paragraphs of this section. In order to avoid any confusion, paragraph (B) includes the provision that articles in the possession of any practitioner shall be deemed to be held for sale.

This section is thus virtually the same as section III of the injunction currently in effect and affirmed by the Court of Appeals for this Circuit. United States v. Diapulse Corporation of America, 485 F.2d 677 (C.A. 2, 1973). Thus, the defendant can hardly be heard to complain that this section of the Government's proposed injunction imposes substantially greater restraints than those currently in effect.

E. Proposed Section V.

With respect to the provision of the permanent injunction currently in effect, this Court, at p. 35 of its May 7 opinion, directed that the reference to the labeling provision, 21 CFR 1.106(d), should be clarified and expanded to make clear that it covers any device covered by the injunction and further directed that:

... consideration should be given to the matter of requiring defendants to clear any medical modility that they desire to sponsor or disseminate in this country. It should be understood that the advance clearance requirement is not normally required for devices but is exceptionally required in this case and consciously borrows from new drug procedures.

In accord with this direction, the Government's proposed injunction revises and expands the provision currently in effect and would prohibit the shipment or modification of Diapulse devices, as defined by section III of the proposed injunction, unless and until the defendant obtains FDA approval of relabeling. In accord with the Court's direction, paragraph (B) of this section defines adequate scientific evidence in much the same terms as substantial evidence is defined in the new drug provision. 21 U.S.C. 355(d) [last sentence]. Similarly, and in order to assure that the defendant has the opportunity to conduct legitimate research with the Diapulse device, paragraph (C) of this section provides for the exemption of shipments of devices intended for investigational use, substantially incorporating the requirements of the new drug procedures. 21 U.S.C. 355(i).

Furthermore, the Court's May 7 opinion recognizes the importance of avoiding the destruction of all existing Diapulse devices if that is possible without compromise of the principle of the Connecticut decision and of Judge Rosling's decision. May 7 opinion, p. 33. In accord with this direction, paragraph (B) of section V provides that the defendant shall cause all articles of device Diapulse (including Diapulse and P/EmF devices and kits) to be returned to the defendant

GOVERNMENT'S MEMORANDUM

to be brought into compliance with the law under FDA supervision. This provision is clearly justified by the evidence showing that the firm has intended to convert previously shipped Diapulse devices despite knowledge of FDA's explicit objections to the modification.

Since the Court has directed that the revised injunction apply to Diapulse devices previously shipped [May 7 opinion, p. 34], it is reasonable and justified to propose that the defendant be required to have all previously shipped Diapulse devices, P/EmF devices and kits returned to its possession to be brought into compliance with the law under FDA supervision. Similar relief requiring the return of articles violative under the Act and shipped in interstate commerce was granted in United States v. Dianovin Pharmaceuticals, 342 F. Supp. 724 (D. P.R., 1972), aff'd 475 F.2d 100 (C.A. 1, 1973); United States v. Lit Drug Company, 333 F. Supp. 990 (D. N.J., 1971); United States v. Lanpar Company, 293 F. Supp. 147 (N.D. Tex., 1968). Such relief accords with the long recognized power of the court in equity to provide complete relief in the light of statutory purposes. Mitchell v. Robert De Mario Jewelry, Inc., 361 U.S. 288 (1960); Porter v. Warner Holding Co., 328 U.S. 395 (1946).

F. Proposed Section VI.

This section requires the defendant to notify the Food and Drug Administration of each of the facilities it utilizes in manufacturing or storing medical devices. This section also authorizes FDA's access to facilities and records for purposes of inspection.

While the defendant objects to these provisions [Memorandum, p. 3] the defendant's president, Jesse Ross, acknowledged the refusal of two Food and Drug Administration inspections following the entry of the permanent injunction in July 1972. Tr. 1043-44. The evidence presented by the Government shows that at the same time, the defendant was engaged in the distribution of modification kits for Diapulse

GOVERNMENT'S MEMORANDUM

devices which had been previously shipped in interstate commerce.

These activities were described by this Court as "evasion ... of the strictures of the permanent injunction and its purpose". May 7 opinion, p. 30.

Thus, in order to fully implement the requirements of the Government's proposed injunction, the Court should specify FDA's inspection authority under the injunction. Similarly, in order to effectively implement the inspection authority, the defendants should be required to notify FDA of each of its facilities utilized in manufacturing medical devices. As the record before the Court indicates, the defendant's president, Jesse Ross, was unable to testify during cross-examination as to the location of one of two warehouses utilized by the defendant. An injunction requirement to require the submission to FDA of such information is clearly justified.

G. Proposed Section VII.

This section requires the defendant to provide notice in a form approved by FDA of the Court's decision and of the provisions of the revised injunction. Notification to users would be required to be sent by receipted mail and notification to distributors and persons engaged in testing or research would be required to be sent by certified mail. Submission to the United States Attorney of a list of all such persons so notified would be required. This is in accord with the Court's direction at p. 35 of its May 7 opinion that a new section or sections, functioning as section V of the current decree be in the amended decree. The purpose of the section is to advise persons of the provisions of the injunction entered by the Court and to advise the United States Attorney of the identity of the persons so notified.

III

CONCLUSION

For the foregoing reasons, the permanent injunction currently in effect should be revised and modified as proposed by the Government.

Respectfully submitted,

DAVID A. TRAGER
United States Attorney

By: _____
CYRIL HYMAN
Assistant United States Attorney

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DEFENDANT'S SUPPLEMENTAL MEMORANDUM

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

-against-

Civil No. 68-C-391

DIAPULSE CORPORATION OF AMERICA,
also known as THE DIAPULSE MANU-
FACTURING CORPORATION OF AMERICA,
a corporation,

Defendant.

SUPPLEMENTAL MEMORANDUM IN BEHALF OF
DEFENDANT ON RESETTLEMENT OF JUDGMENT

This supplement is respectfully submitted to
avoid a possible inference from my omission, at the oral
argument on July 3, to specifically reiterate the objec-
tions to FDA's proposed preconditions, in Section V(C)(2)
and (3) on pages 7-8 of its submission, to shipments "for
investigational or research purposes".

The tenor of my oral argument was total oppos-
ition to the judgment proposed by the FDA and advocacy
of the judgment proposed by the defendant as urged in
my memorandum of June 21. In that memorandum I referred
to FDA's proposals in regard to research, as well as con-

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DEFENDANT'S SUPPLEMENTAL MEMORANDUM

version of outstanding Diapulses, as intended to defeat both experimentation and conversion "by circumscribing each of those authorizations with such onerous restrictions including FDA advance approval, as to render the authorizations inoperative". Of course, the omission of specific reiteration is not to be taken as a weakening or withdrawal.

On the contrary, I respectfully suggest that the position taken by the FDA in respect to complying with the mandate of the Court of Appeals in the action under the Freedom of Information Act, makes it clearer than ever that any prerequisite of approval by the FDA of any submission by the defendant will result in complete frustration. Although piously avowing a "policy of fullest possible disclosure under the Freedom of Information Act", FDA has submitted an affidavit that it must have not less than 60 days plus not less than 30 days plus not less than 120 days - a total of 210 days or seven months - to make available such of the called for records as the agency deems disclosable and then only on the prepayment of an amount it would determine as "search fees" and freight charges.

Is it reasonable to expect that under its pro-

DEFENDANT'S SUPPLEMENTAL MEMORANDUM

posed Section V(A) and (B) FDA ever would authorize a conversion of a Diapulse into a diathermy, when its precondition is that defendant must first support the standard labeling of diathermy modalities by submitting "well controlled investigations" which the FDA will deem adequate as if diathermy devices were a new drug? Likewise, what likelihood is there of a pre-clearance for investigational use under the terms proposed at pages 7-8 of FDA's submission? Moreover, what is the need or justification for those provisions?

Respectfully submitted,

Copal Mintz
COPAL MINTZ
Attorney for Defendant.

July 5, 1974.

PERMANENT INJUNCTION, DOOLING, J.,
DATED 7/17/74 FILED 7/18/74

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

-----X
UNITED STATES OF AMERICA,

Plaintiff, : 68 C 391
-against- : PERMANENT INJUNCTION

DIAPULSE CORPORATION OF AMERICA,
also known as THE DIAPULSE MANU-
FACTURING CORPORATION OF AMERICA,
a corporation,

Defendant.

-----X
In accordance with the Findings of Fact and Conclusions
of Law heretofore made by this Court on December 8, 1971,
June 9, 1972, and May 7, 1974; after trial; it is
ORDERED, ADJUDGED, AND DECREED as follows:

I

This Court has jurisdiction over the subject matter
herein and parties hereto and the Complaint for Injunction
states a valid cause of action against the defendant under
the Federal Food, Drug, and Cosmetic Act.

II

For the purposes of this Injunction, the following
terms shall be defined as follows:

(A) The term "interstate commerce" means (1) commerce
between any State or Territory and any place outside thereof,
other than exports permitted under 21 U.S.C. 38(d),
and (2) commerce within the District of Columbia or within
any other Territory not organized with a legislative body;

2.

(B) The term "device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure of any function of the body of man or other animals; the term "device" includes defined devices both in whole and in part, whether assembled or unassembled and components, parts, accessories, assemblies and subassemblies usable or adaptable to create defined devices or to convert other devices into defined devices;

(C) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any device;

(D) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any device or any of its containers or wrappers, or (2) accompanying such device;

(E) The term "prohibited device" as hereinafter used means and includes all and any of the following:

(1) Any device known as Diapulse or by any other designation, including Models D-100, D-100J, D-101, D-102, or D-103, heretofore shipped, sold, leased, or introduced or delivered for introduction into interstate commerce;

(2) Any device known as P/EmF or by any other

designation, including any device defined in section II(E)(1) above, as modified to convert the said device to a P/EMF device;

(3) Any device consisting of an electronic instrument incorporating an electromagnetic generator which produces or is adaptable to produce pulsed, short-wave, high frequency electromagnetic energy unless; (1) the peak power available at any setting of the said device does not exceed twice the average wattage at such setting; and (2) the said device is capable of raising the temperature of human tissue at a depth of 2 inches in the thigh muscle of living human subjects from a core body temperature of 98.6°F to 104°F in 20 minutes or less at a majority of its operational settings; and (3) the said device is capable of raising the temperature of human tissue at a depth of 2 inches in the thigh muscle of living human subjects to a range of temperatures of 104°F to 113°F at a series of readily selected settings of the said device.

III

The defendant, Diapulse Corporation of America, a corporation, and each and all of its officers, agents, servants, employees, and representatives, and those persons in active concert or participation with them who receive actual notice of this injunction by personal service or otherwise be and they are hereby permanently enjoined under 21 U.S.C. 332(a) from directly or indirectly causing any of the following acts with respect to any prohibited device, since such acts would result in the said device being misbranded within the meaning

4.

of 21 U.S.C. 352(a) and (f)(1) and would constitute violations of 21 U.S.C. 331(a) and (k):

(A) Causing to be introduced or delivered for introduction into interstate commerce any of said prohibited devices which:

(1) Bears or is accompanied by any item of written, printed, or graphic matter, including but not limited to leaflets containing directions, leaflets containing references to published medical or scientific literature, warranty brochures, advertising brochures, advertising layouts, reprints of speeches or reprints of published articles, which contain instructions for the operation, modification or alteration of any of said prohibited devices which contain statements or representations that directly or indirectly imply, represent, suggest or create the impression that any of said prohibited devices are adequate and effective in the cure, mitigation, treatment or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals;

(2) Fails to state in its labeling all of the purposes, conditions, and diseases for which any of said prohibited devices are intended for use, and for which any of said prohibited devices are represented by any means by said defendant to prospective dealers, purchasers, renters or lessees; or which fails to state in its labeling the effects of the prohibited device on the body of man or other animals;

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its mode or mechanism of action; route, methods, frequency and duration of administration; and any relevant hazards, contraindications, side effects and precautions necessary for safe use;

(3) Is intended for delivery to any person who said defendant has good cause to believe does or will represent by any means to prospective dealers, purchasers, renters or lessees of any of said prohibited devices that said prohibited devices are adequate and effective for the cure, mitigation, treatment or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals;

(B) Causing any act to be done with respect to any of said prohibited devices while any of said prohibited devices are held for sale after shipment in interstate commerce, which act results in any of said prohibited devices being misbranded in any of the ways specified in parts (A)(1), (2) and (3) of this section: Provided, that any of said prohibited devices in the possession of any practitioner licensed by law to use or order the use of any of said prohibited devices shall be deemed to be held for sale.

IV

(A) The defendant, Diapulse Corporation of America, a corporation, and each and all of its officers, agents, servants, employees, and representatives, and those persons in active concert or participation with them who receive actual notice

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of this injunction by personal service or otherwise are hereby permanently enjoined from causing to be shipped, sold, leased, introduced or delivered for introduction into interstate commerce any prohibited devices unless and until the said defendant assembles adequate scientific evidence on which labeling of said prohibited devices is to be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug, and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106(d), and the defendant submits such evidence and such proposed labeling to the Food and Drug Administration, Rockville, Maryland, and obtains approval thereof in writing: Provided, that where any such submission involves any device other than one defined by section II (E)(1) above, a sample of the said device shall be made available for delivery at defendant's expense to the Food and Drug Administration, Rockville, Maryland, for examination and testing.

(B) As used in this section, the term "adequate scientific evidence" means evidence consisting of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by scientific training and experience to evaluate the effectiveness of the device involved, on the basis of which it could fairly and responsibly be concluded by such experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling thereof, unless upon the

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defendant's petition the Food and Drug Administration determines and advises the defendant in writing that other valid scientific evidence is sufficient to establish the effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof: Provided, that for the purposes of this paragraph the term "well-controlled investigations" shall be deemed to mean investigations conducted according to the principles specified by the regulation 21 CFR §314.111(a)(5)(ii)(a)(1)-(5) [37 F.R. 11727, March 29, 1974, recodifying 21 CFR §130.12(a)(5)(ii)(a)(1)-(5) (1973)].

(C) A shipment or other delivery for investigational or research purposes of any of said prohibited devices shall not be subject to sections III and IV(A) herein, provided that the following conditions are met:

(1) The label of each device bears the statement "For Investigational Use"; and

(2) The defendant, not less than 30 days before the proposed shipment, submits in writing to the Food and Drug Administration, Rockville, Maryland, (a) the name and address of the carrier to be utilized for the proposed shipment, (b) a full and complete description (including schematic diagram of its circuitry) of the device to be shipped, (c) the number of devices to be shipped and the serial number of each, and (d) a detailed protocol showing that the proposed

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investigation will be conducted according to the principles specified by 21 U.S.C. 355(i) in that such protocol shall include the name, address, and a complete statement of the qualifications of each investigator, the specific nature of the investigation to be conducted, the approximate number of subjects, a certification that the informed consent of all human subjects involved in the investigation will be obtained, the estimated duration of the investigation, and the intervals (not greater than 6 months) at which progress reports showing the results of the investigation will be submitted to the Food and Drug Administration.

(3) If the Food and Drug Administration determines that (a) the information submitted is incomplete, false, or misleading; (b) the device is not in fact intended to be used exclusively for investigational purposes; (c) the investigation, if conducted as proposed, would not meet the standards for adequate scientific evidence and investigations as specified by this paragraph and paragraph (B) of this section; or (d) the person (including institutional persons) undertaking the investigation is not qualified by training and experience to conduct the investigation or evaluate the effectiveness of the device, plaintiff may apply at the foot of this injunction (pursuant to Section VII) for an order specifically extending the prohibitions of this injunction to such shipment or delivery.

(D)(1) The defendants shall within 90 days of the date of entry of this Injunction cause the prohibited devices of Section II(E)(2) heretofore introduced or delivered for introduction into interstate commerce and all labeling accompanying said prohibited devices, heretofore introduced or delivered for introduction into interstate commerce, to be returned to the possession of the defendant by providing notice in writing to each person having possession of any of said devices advising such persons to return all such devices and labeling at defendant's expense to the defendant at its headquarters at New Hyde Park, New York, or to other suitable facilities as approved by the Food and Drug Administration; a copy of said notice to be transmitted to the Food and Drug Administration, Rockville, Maryland, on the date such notice is first transmitted to the person having possession of said devices.

(2) For the purpose of accounting for the returned labeling, for each of the said returned devices, and for each of the said prohibited devices which cannot be returned by reason of previous destruction or because it is in the custody of a United States District Court, or is otherwise unavailable, the said defendant shall within 120 days of the date of entry of this Injunction submit to the Food and Drug Administration, Rockville, Maryland, separate listings in writing as follows:

(a) for each of said returned devices, the model number, serial number, and, the location to which returned; (b) for each of said devices unavailable to be returned, the model number, serial number, and the reason for its unavailability; (c) for accompanying labeling, the location to which returned.

(3) (a) The defendant shall, within 180 days of its compliance with the provisions of paragraphs (D)(1) and (2) of this section, determine whether to attempt to bring the said returned devices into compliance with the law by relabeling or modification pursuant to the provisions of paragraph (A) of this section or whether to destroy or salvage (for other than device purposes) the said returned devices, and within said 180 days (or within such additional time as authorized by the Food and Drug Administration) the defendant shall give written notice to the Food and Drug Administration Rockville, Maryland, that defendant is prepared to bring the returned devices into compliance with the law or to effect their destruction or salvaging (for other than device purposes under the supervision of a duly authorized representative of the Food and Drug Administration: Provided, that the defendant shall not commence such compliance or destruction or salvaging operations until it has received authorization in writing to do so from the Food and Drug Administration, Rockville, Maryland.

(b) The defendant shall under no circumstances whatsoever ship, sell, offer for sale, or otherwise dispose of any part of said returned devices until duly authorized

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representatives of the Food and Drug Administration shall have had free access thereto in order to make any examination or inspections that are deemed necessary, and shall in writing have released said devices for shipment, sale, or other disposition.

v

The defendant, Diapulse Corporation of America, a corporation, shall:

(A) Submit to the Food and Drug Administration, Rockville, Maryland, within 10 days of the date of entry of this Injunction, a written list stating the complete street address, including post office zip code, of each of the offices, plants, factories, warehouses, storage facilities, or other establishments used by the said defendant for the manufacturing, assembling, processing, packing, transporting, or holding of any device or which is used by the said defendant to hold any equipment, finished and unfinished materials, containers, labeling, records, files or other papers bearing on the manufacturing, assembling, processing, packing, transporting, or holding of any devices; and shall thereafter submit notice in writing to the Food and Drug Administration, Rockville, Maryland, as to each disposition or acquisition of such establishments within 10 days of each such occurrence.

(B) Grant duly authorized officers and employees of the Food and Drug Administration free access to any of its offices, plants, factories, warehouses, storage facilities, or other

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establishments at reasonable times during regular working hours, within reasonable limits and in a reasonable manner to inspect such establishment and all pertinent equipment, finished and unfinished materials, containers, and labeling therein; and such inspection may include copying and photographing and shall also extend to all things therein (including records, files, papers, processes and facilities) bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed, transported, or held in such place.

VI

The defendant shall give notice in writing of this Court's decision of May 7, 1974, by submitting within 30 days of the date of the entry of this Injunction a form of notice to the Food and Drug Administration, Rockville, Maryland, for approval in writing, and within 30 days of receiving such approval, shall send by receipted mail a copy of such notice and a copy of this Injunction to each person known to the defendant to have purchased or leased, or to have in his possession any of said prohibited devices, and shall send by certified mail, return receipt requested, a copy of such notice and a copy of this Injunction to each of the officers, agents, and employees of the defendant or of any subsidiaries owned in whole or in part by the defendant, and to each person who has been or is a distributor of any of said prohibited

PERMANENT INJUNCTION, DOOLING, J.,
DATED 7/17/74 FILED 7/18/74

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devices or a sales representative for any of said devices, and to all persons now in active concert or participation with said defendant, assisting or participating in the sale, promotion, or manufacture of said devices, and to all persons who have been or are now engaged in testing or research involving any of said prohibited devices; and defendant within 40 days from the date of entry of this Injunction, shall advise in writing the United States Attorney, Eastern District of New York, Brooklyn, New York, of the name and address of each person so notified; and defendant shall supply a copy of said notice and a copy of this Permanent Injunction to all persons in the future in active concert or participation with said defendant, assisting or participating in the sale, promotion, or manufacture of said devices, and to all persons known to the defendant to be engaged in testing or research involving any of said prohibited devices.

VII

This Court retains jurisdiction of this case for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate.

VIII

The plaintiff, United States of America, shall recover

PERMANENT INJUNCTION, DOOLING, J.,
DATED 7/17/74 FILED 7/18/74

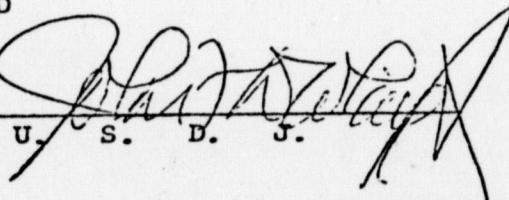
14.

from the defendant, the costs of this action, to be taxed
by the Clerk of the Court.

Brooklyn, New York

July 17, 1974.

APPROVED



John Dooling

U. S. D. J.

CLERK

MOTION FOR STAY PENDING APPEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

68 C 391

-against-

DIAPULSE CORPORATION OF AMERICA,
also known as THE DIAPULSE MANU-
FACTURING CORPORATION OF AMERICA,
a corporation,

MOTION FOR STAY OF
JUDGMENT PENDING
APPEAL

Defendant.

The defendant moves for a stay, pending the determina-
tion of an appeal from the judgment herein dated July 17,
1974, of

the whole of said judgment

or, alternatively, the following portions there-
of: the proviso in Section III(B); Section IV(D)
and all sub-divisions thereof; and the whole of
Sections V, VI and VIII;

on condition that a timely notice of appeal be filed, the
appeal be timely docketed and it be prosecuted with due
diligence.

Dated: July 18, 1974.

Edward M. Mentz
COPAL MENTZ
Attorney for Defendant
150 Broadway
New York, N. Y. 10038

TO:

The Honorable John F. Dooling, Jr.
Judge U.S.D.C.

David G. Trager, Esq.
U.S. Attorney
Attorney for Plaintiff

ORDER, DOOLING, J., DENYING MOTION FOR STAY

July 19, 1974

The occasion of the order involved and its nature are such as to make the granting of a stay pending appeal inappropriate.

It is ORDERED that the motion for a stay of the judgment in whole or, alternatively, in part, is in all respects denied.

JOHN F. DOOLING, JR.
U.S.D.J.

NOTICE OF APPEAL

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,
Plaintiff,

68 C 391

-against-

DIAPULSE CORPORATION OF AMERICA,
also known as THE DIAPULSE MANU-
FACTURING CORPORATION OF AMERICA,
a corporation,

NOTICE OF APPEAL

Defendant.

Notice is hereby given that DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, defendant above named, hereby appeals to the United States Court of Appeals for the Second Circuit from the judgment, entitled "Permanent Injunction", dated July 17, 1974 and filed July 18, 1974.

Dated: July 23, 1974.

Copal Mintz
Attorney for Defendant
150 Broadway
New York, N. Y. 10038
(212) 227-7070

To:

Clerk of the Court

David G. Trager, Esq.
United States Attorney
Attorney for Plaintiff
U.S. Courthouse
225 Cadman Plaza East
Brooklyn, New York 11201